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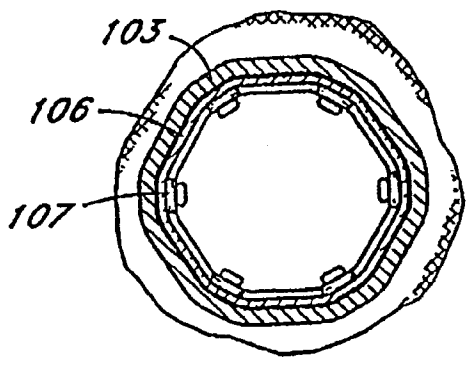

(57) Abstract: The present invention is related to a low profile endoluminal prosthesis. The prosthesis comprises a tubular wire support made from at least two radially expandable segments and an expanded PTFE membrane. The membrane may be applied to both the inner, lumenal surface of the wire support as well as the exterior surface of the wire support. Use of the membrane to secure the segments of the wire cage provides a simple construction having a minimal profile.

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PTFE EMBEDDED LOW PROFILE ENDOLUMINAL PROSTHESIS

Background of the Invention

Field of the Invention

The present invention relates to an endoluminal vascular prosthesis, and in particular, to a self-expanding low profile prosthesis for use in the treatment of abdominal aortic aneurysms.

Description of the Related Art

An abdominal aortic aneurysm is a sac caused by an abnormal dilation of the wall of the aorta, a major artery of the body, as it passes through the abdomen. The abdomen is that portion of the body which lies between the thorax and the pelvis. It contains a cavity, known as the abdominal cavity, separated by the diaphragm from the thoracic cavity and lined with a serous membrane, the peritoneum. The aorta is the main trunk, or artery, from which the systemic arterial system proceeds. It arises from the left ventricle of the heart, passes upward, bends over and passes down through the thorax and through the abdomen to about the level of the fourth lumbar vertebra, where it divides into the two common iliac arteries.

The aneurysm usually arises in the infrarenal portion of the diseased aorta, for example, below the kidneys. When left untreated, the aneurysm may eventually cause rupture of the sac with ensuing fatal hemorrhaging in a very short time. High mortality associated with the rupture led initially to transabdominal surgical repair of abdominal aortic aneurysms. Surgery involving the abdominal wall, however, is a major undertaking with associated high risks. There is considerable mortality and morbidity associated with this magnitude of surgical intervention, which in essence involves replacing the diseased and aneurysmal segment of blood vessel with a prosthetic device which typically is a synthetic tube, or graft, usually fabricated of Polyester, Urethane, DACRON , TEFLON , or other suitable material.

To perform the surgical procedure requires exposure of the aorta through an abdominal incision which can extend from the rib cage to the pubis. The aorta must be closed both above and below the aneurysm, so that the aneurysm can then be opened and the thrombus, or blood clot, and arteriosclerotic debris removed. Small arterial branches from the back wall of the aorta are tied off. The DACRON tube, or graft, of approximately the same size of the normal aorta is sutured in place, thereby replacing the aneurysm. Blood flow is then reestablished through the graft. It is necessary to move the intestines in order to get to the back wall of the abdomen prior to clamping off the aorta.

If the surgery is performed prior to rupturing of the abdominal aortic aneurysm, the survival rate of treated patients is markedly higher than if the surgery is performed after the aneurysm ruptures, although the mortality rate is still quite high. If the surgery is performed prior to the aneurysm rupturing, the mortality rate is typically slightly less than 10%. Conventional surgery performed after the rupture of the aneurysm is significantly higher, one study reporting a mortality rate of 66.5%. Although abdominal aortic aneurysms can be detected from routine examinations, the patient does not experience any pain from the condition. Thus, if the patient is not receiving routine examinations, it is possible that the aneurysm will progress to the rupture stage, wherein the mortality rates are significantly higher.

Disadvantages associated with the conventional, prior art surgery, in addition to the high mortality rate include the extended recovery period associated with such surgery; difficulties in suturing the graft, or tube, to the aorta; the loss

of the existing aorta wall and thrombosis to support and reinforce the graft; the unsuitability of the surgery for many patients having abdominal aortic aneurysms; and the problems associated with performing the surgery on an emergency basis after the aneurysm has ruptured. A patient can expect to spend from one to two weeks in the hospital after the surgery, a major portion of which is spent in the intensive care unit, and a convalescence period at home from two to three months, particularly if the patient has other illnesses such as heart, lung, liver, and/or kidney disease, in which case the hospital stay is also lengthened. The graft must be secured, or sutured, to the remaining portion of the aorta, which may be difficult to perform because of the thrombosis present on the remaining portion of the aorta. Moreover, the remaining portion of the aorta wall is frequently friable, or easily crumbled.

Since many patients having abdominal aortic aneurysms have other chronic illnesses, such as heart, lung, liver, and/or kidney disease, coupled with the fact that many of these patients are older, the average age being approximately 67 years old, these patients are not ideal candidates for such major surgery.

More recently, a significantly less invasive clinical approach to aneurysm repair, known as endovascular grafting, has been developed. Parodi, et al. provide one of the first clinical descriptions of this therapy. Parodi, J.C., et al., "Transfemoral Intraluminal Graft Implantation for Abdominal Aortic Aneurysms," 5 Annals of Vascular Surgery 491 (1991). Endovascular grafting involves the translumenal placement of a prosthetic arterial graft within the lumen of the artery.

In general, transluminally implantable prostheses adapted for use in the abdominal aorta comprise a tubular wire cage surrounded by a tubular sleeve made of polytetrafluoroethylene (PTFE) or DACRON®. Both balloon expandable and self expandable support structures have been proposed. Endovascular grafts adapted to treat both straight segment and bifurcation aneurysms have also been proposed.

Notwithstanding the foregoing, there remains a need for a structurally simple, easily deployable endovascular prosthesis having a low profile adapted for translumenal delivery. Moreover, this need extends to prosthesis adaptable to span either a straight or bifurcated abdominal aortic aneurysm. Preferably, the tubular prosthesis can be self expanded at the site to treat the abdominal aortic aneurysm, and exhibits flexibility to accommodate nonlinear anatomies and normal anatomical movement.

Summary of the Invention

The present invention is related to a low profile endoluminal prosthesis. In a preferred embodiment of the present invention, the prosthesis comprises a tubular wire support and a membrane. The tubular wire support has proximal and distal ends and a central lumen extending therebetween. The wire support creates an inner, lumenal surface and an outer, exterior surface. The wire support is formed from at least two axially adjacent tubular segments, each segment comprising a series of proximal and distal bends connected by a length of wire. The wire support is radially compressible into a first, reduced cross sectional configuration for implantation into a body lumen, and self expandable to a second, enlarged cross sectional configuration at a treatment site in a body lumen.

The membrane is formed from at least one layer of a polymeric film and adhered to at least a portion of each adjacent segment of the wire support. Thus, by adhering to adjacent segments, the membrane at least inhibits, and preferably, substantially prevents these segments from moving axially relative to one another.

In one variation, the endoluminal prosthesis has at least three segments. In another variation, the prosthesis has at least five segments. The segments that make up the wire support may comprise from about 4 proximal bends to about 12 proximal bends.

In a preferred embodiment of the present invention, the polymeric film comprises expanded polytetrafluoroethylene (ePTFE). Moreover, at least one layer of ePTFE film has fibrils oriented substantially in a single direction. In one preferred variation, the membrane is formed from more than one layer of ePTFE film, wherein the layers of ePTFE are cross-laminated such that the fibrils from one layer are angularly offset in relation to the fibrils from an adjacent layer. The cross-laminated layers of ePTFE film may be offset at an angle of between 0 and 180°.

The endoluminal prosthesis of the present invention also comprises an adhesive for adhering the membrane to the wire support. Preferably, the adhesive is a thermoplastic polymer adhesive, such as for example, fluoroethylene polymer (FEP).

In one preferred variation of the endoluminal prosthesis, two membranes are bound to at least a portion of each adjacent segment of the tubular wire support. The first membrane is bound along the lumenal surface and a second membrane is bound along the exterior surface. Consequently, the wire support is substantially embedded between the first and second membranes. Besides adhering to the FEP coated wire, the first membrane is preferably adhered at least partially to the second membrane through openings between the wire support.

The first and second membranes are formed from an equal number of layers of ePTFE film. Each membrane may have between 2 and 20 layers of ePTFE film. The ePTFE film has fibrils oriented substantially in a single direction. This produces a stretch direction in which the film is disposed to stretch. In one preferred embodiment of the present invention, the layers of ePTFE film which form each membrane are cross-laminated such that the fibrils from one layer are angularly offset in relation to the fibrils from an adjacent layer. The resulting advantage is that the membrane produced is stronger with more equivalent give in all directions.

A bifurcated endoluminal prosthesis is disclosed in accordance with another variation of the present invention. The bifurcated prosthesis comprises three tubular wire supports, a body graft tube and first and second branch graft tubes. The first and second branch graft tubes may be attached by a pivotable linkage to the body graft tube, thereby forming a flexible y-shaped prosthesis. Each tube comprises at least two axially adjacent tubular segments made from a wire shaped into a series of proximal and distal bends. The bifurcated prosthesis also has a membrane formed from at least one layer of a polymeric film. As discussed above, the membrane is adhered to at least a portion of the adjacent tubular segments in each wire support. Consequently, the membrane at least limits and preferably inhibits movement between adjacent segments.

A method of making an endoluminal prosthesis is also disclosed in accordance with the present invention. The method comprises the steps of: (1) providing a length of wire, (2) forming the wire into at least two zig-zag

segments, (3) rolling the formed wire about an axis to produce a tubular wire support comprising a series of tubular elements positioned along the axis, the tubular wire support having a lumenal surface and an exterior surface, (4) coating at least one of the lumenal and exterior surfaces of the tubular wire support with a thermoplastic adhesive, (5) contacting an ePTFE membrane to each of the at least one adhesive-coated surfaces of the tubular wire support, (6) heating the coated tubular wire support and ePTFE membrane to a temperature above a melting point of the thermoplastic adhesive, and (7) cooling the resulting assembly.

Preferably, the method includes contacting an ePTFE membrane to each of the lumenal and exterior surfaces of the tubular wire support, such that the wire support is substantially embedded between the ePTFE membranes after the heating and cooling steps.

Brief Description of the Drawings

Fig. 1 is a schematic representation of a straight segment vascular prosthesis in accordance with the present invention, positioned within a symmetric abdominal aortic aneurysm.

Fig. 2 is an exploded view of an endoluminal vascular prosthesis in accordance with the present invention, showing a self expandable wire support structure separated from an outer tubular sleeve.

Fig. 3 is a plan view of a formed wire useful for rolling about an axis into a multi-segment support structure in accordance with the present invention.

Fig. 4 is an enlarged detail view of a portion of the formed wire illustrated in Fig. 3.

Fig. 5 is a schematic view of a portion of a wire cage wall, illustrating folded link connections between adjacent apexes.

Fig. 6 is an exploded view of two opposing apexes dimensioned for one embodiment of the folded link connection of the present invention.

Fig. 7 is an enlarged view of a folded link, taken along the lines 7-7 in Fig. 5.

Fig. 8 is a cross-sectional view taken along the line 8-8 in Fig. 7.

Fig.'s 6A, 7A, 8A, 7B, 8B, 7C, and 7D illustrate alternate embodiments of a folded link constructed from an opposing apex pair.

Fig. 9 is a partial view of a junction between two adjacent tubular segments, illustrating oppositely oriented folded links in accordance with the present invention.

Fig. 10 is a cross-section taken along the line 10-10 in Fig. 9.

Fig. 11 is a schematic view of a portion of a wall of a graft, laid out flat, illustrating an alternating folded link pattern.

Fig. 12 is a wall pattern as in Fig. 11, illustrating a multi-zone folded link pattern.

Fig.'s 12A through 12C illustrate an alternate wall pattern, which permits axially staggered links between adjacent graft segments.

Fig.'s 13A, through 13C show alternative zig-zag wire support configurations that vary from the support illustrated in Fig. 3.

Fig. 14 is a cross-sectional view taken through a portion of a prosthesis in which a wire support is embedded in an ePTFE wall.

Fig.'s 15A & B are schematic views of a portion of a wall of a graft, laid out flat, illustrating two alternative wire support configurations having spot welds between lumenal and exterior layers of a polymeric membrane.

Fig. 15C is a cross-sectional view through the wall taken along line C-C in Fig.'s 15 A & B.

Fig. 16 is a schematic illustration of a straight segment delivery catheter in accordance with the present invention, positioned within an abdominal aortic aneurysm.

Fig. 17 is an illustration as in Fig. 16, with the straight segment endoluminal prosthesis partially deployed from the delivery catheter.

Fig. 18 is a schematic representation of the abdominal aortic anatomy, with an endoluminal vascular prostheses of the present invention positioned within each of the right renal artery and the right common iliac.

Fig. 19 is a schematic representation of a straight segment graft in accordance with a further embodiment of the present invention, with side openings to permit renal perfusion.

Fig. 20 is a schematic representation of a bifurcated vascular prosthesis in accordance with the present invention, positioned at the bifurcation between the abdominal aorta and the right and left common iliac arteries.

Fig. 21 is a cross-sectional view of the implanted graft taken along the lines 20-20 of Fig. 20.

Fig. 22 is an exploded view of the bifurcated vascular prosthesis in accordance with the present invention, showing a two-part self expandable wire support structure separated from an outer tubular sleeve.

Fig. 23 is a plan view of formed wire useful for rolling about an axis into an aortic trunk segment and a first iliac branch segment support structure in accordance with the present invention.

Fig. 24 is a schematic representation of another embodiment of the wire support structure for the bifurcated vascular prosthesis of the present invention, showing a main body support structure and separate branch support structures.

Fig. 25 is a schematic representation of the three-part wire support structure as in Fig. 24, illustrating the sliding articulation between the branch supports and the main body support.

Fig. 26 is a plan view of formed wire useful for rolling about an axis to form a branch support structure in accordance with the three-part support embodiment of the present invention shown in Fig. 24.

Fig.'s 27A, 27B and 27C are enlargements of the apexes delineated by lines A, B and C, respectively, in Fig. 26.

Detailed Description of the Preferred Embodiment

Referring to Fig. 1, there is disclosed a schematic representation of the abdominal part of the aorta and its principal branches. In particular, the abdominal aorta 30 is characterized by a right renal artery 32 and left renal artery 34. The large terminal branches of the aorta are the right and left common iliac arteries 36 and 38. Additional vessels (e.g., second lumbar, testicular, inferior mesenteric, middle sacral) have been omitted for simplification. A generally symmetrical aneurysm 40 is illustrated in the infrarenal portion of the diseased aorta. An expanded straight segment endoluminal vascular prosthesis 42, in accordance with the present invention, is illustrated spanning the aneurysm 40.

The endoluminal vascular prosthesis 42 includes a polymeric sleeve 44 and a tubular wire support 46, which are illustrated *in situ* in Fig. 1. The sleeve 44 and wire support 46 are more readily visualized in the exploded view shown in Fig. 2. The endoluminal prosthesis 42 illustrated and described herein depicts an embodiment in which the polymeric sleeve 44 is situated concentrically outside of the tubular wire support 46. However, other embodiments may include a sleeve situated instead concentrically inside the wire support or on both of the inside and the outside of the wire support. Alternatively, the wire support may be embedded within a polymeric matrix which makes up the sleeve. Regardless of whether the sleeve 44 is inside or outside the wire support 46, or both inside and outside, the sleeve may be attached to the wire support by any of a variety of means, including laser bonding, adhesives, clips, sutures, dipping or spraying or others, depending upon the composition of the sleeve or membrane 44 and overall graft design.

In one preferred embodiment, the tubular wire support 46 is formed from a continuous single length of round or flattened wire. Alternatively, two or more wire lengths can be secured together to produce the wire support 46. The wire support 46 is preferably formed in a plurality of discrete tubular segments 54, connected together and oriented about a common axis. Each pair of adjacent segments 54 may be connected by a connector 66 as illustrated in Fig. 3. The connectors 66 collectively produce a generally axially extending backbone which adds axial strength to the prosthesis 42. Adjacent segments can be connected both by the backbone, as well as the interlocking junction disclosed below. Additional structures, including circumferentially extending sutures, solder joints, and wire loops may also be used. Alternatively, in one preferred embodiment, adjacent wire cage segments may be held together by the polymeric sleeve in which the cage is embedded. This embodiment is detailed below.

The segmented configuration of the tubular wire support 46 facilitates a great deal of flexibility. Each segment 54, though joined to adjacent segments, may be independently engineered to yield desired parameters. Each segment may range in axial length from about 0.3 to about 5 cm. Generally, the shorter their length the greater the radial strength. An endoluminal prosthesis may include from about 1 to about 50 segments, preferably from about 3 to about 10 segments. For example, while a short graft patch, in accordance with the invention, may comprise only 2 segments and span a total of 2 to 3 cm, a complete graft may comprise 4 or more segments and span the entire aortic aneurysm. In addition to the flexibility and other functional benefits available through employment of different length segments, further flexibility can be achieved through adjustments in the number, angle, or configuration of the wire bends associated with the tubular support.

In addition to having differing expanded diameters in different zones of the prosthesis 42, different zones can be provided with a different radial expansion force, such as ranging from about .2 lbs. to about .8 lbs. In one embodiment, the proximal zone 55 is provided with a greater radial force than the central zone 57 and/or distal zone 59. The greater radial force can be provided in any of a variety of manners discussed elsewhere herein, such as through the use of an additional one or two or three or more proximal bends 60, distal bends 62 and wall sections 64 compared to a reference segment 54 in the central zone 57 or distal zone 59. Alternatively, additional spring force can be achieved in the proximal zone 55 through the use of the same number of proximal bends 60 as in the rest of the prosthesis, but with a heavier gauge wire.

The wire may be made from any of a variety of different alloys, such as elgiloy, Nitinol or MP35N, or other alloys which include nickel, titanium, tantalum, or stainless steel, high Co-Cr alloys or other temperature sensitive materials. For example, an alloy comprising Ni 15%, Co 40%, Cr 20%, Mo 7% and balance Fe may be used. The tensile strength of suitable wire is generally above about 300 Ksi and often between about 300 and about 340 Ksi for many embodiments. In one embodiment, a Chromium-Nickel-Molybdenum alloy such as that marketed under the name Conichrom (Fort Wayne Metals, Indiana) has a tensile strength ranging from 300 to 320 K psi, elongation of 3.5 - 4.0%. The wire may be treated with a plasma coating and be provided with or without additional coatings such as PTFE, Teflon, Perlyne and drugs.

In addition to segment length and bend configuration, discussed above, another determinant of radial strength is wire gauge. The radial strength, measured at 50% of the collapsed profile, preferably ranges from about 0.2 lb to 0.8 lb, and generally from about 0.4 lb to about 0.5 lb. or more. Preferred wire diameters in accordance with the present invention range from about 0.004 inches to about 0.020 inches. More preferably, the wire diameters range from about 0.006 inches to about 0.018 inches. In general, the greater the wire diameter, the greater the radial strength for a given wire layout. Thus, the wire gauge can be varied depending upon the application of the finished graft, in combination with/or separate from variation in other design parameters (such as the number of struts, or proximal bends 60 and distal bends 62 per segment), as will be discussed. A wire diameter of approximately 0.018 inches may be useful in a graft having four segments each having 2.5 cm length per segment, each segment having six struts intended for use in the aorta, while a smaller diameter such as 0.006 inches might be useful for a 0.5 cm segment graft having 5 struts per segment intended for the iliac artery. The length of cage 42 could be as long as about 28 cm.

In one embodiment of the present invention, the wire diameter is tapered from the proximal to distal ends. Alternatively, the wire diameter may be tapered incrementally or stepped down, or stepped up, depending on differing radial strength requirements along the length of the graft for each particular clinical application. In one embodiment, intended for the abdominal aortic artery, the wire has a cross-section of about 0.018 inches in the proximal zone 55 and the wire tapers down to a diameter of about 0.006 inches in the distal zone 59 of the graft 42. End point dimensions and rates of taper can be varied widely, within the spirit of the present invention, depending upon the desired clinical performance.

Referring to Fig. 3, there is illustrated a plan view of a single formed wire used for rolling about a longitudinal axis to produce a four segment straight tubular wire support. The formed wire exhibits distinct segments, each corresponding to an individual tubular segment 54 in the tubular support (see Fig.'s 1 and 2).

Each segment has a repeating pattern of proximal bends 60 connected to corresponding distal bends 62 by wall sections 64 which extend in a generally zig-zag configuration when the segment 54 is radially expanded. Each segment 54 is connected to the adjacent segment 54 through a connector 66, except at the terminal ends of the graft. The connector 66 in the illustrated embodiment comprises two wall or strut sections 64 which connect a proximal bend 60 on a first segment 54 with a distal bend 62 on a second, adjacent segment 54. The connector 66 may additionally be provided with

a connector bend 68, which may be used to impart increased radial strength to the graft and/or provide a tie site for a circumferentially extending suture.

Referring to Fig. 4, there is shown an enlarged view of the wire support illustrating a connector 66 portion between adjacent segments 54. In the embodiment shown in Fig. 4, a proximal bend 60 comprises about a 180 degree arc, having a radial diameter of (w) (ranging from .070 to .009 inches), depending on wire diameter followed by a relatively short length of parallel wire spanning an axial distance of d1. The parallel wires thereafter diverge outwardly from one another and form the strut sections 64, or the proximal half of a connector 66. At the distal end of the strut sections 64, the wire forms a distal bend 62, preferably having identical characteristics as the proximal bend 60, except being concave in the opposite direction. The axial direction component of the distance between the apexes of the corresponding proximal and distal bends 60, 62 on a given strut section 64 is referred to as (d) and represents the axial length of that segment. The total expanded angle defined by the bend 60 and the divergent strut sections 64 is represented by α. Upon compression to a collapsed state, such as when the graft is within the deployment catheter, the angle α is reduced to α'. In the expanded configuration, α is generally within the range of from about 35° to about 45° for a six apex section having an axial length of about 1.5 cm or 2 cm and a diameter of about 25 mm or 28 mm. The expanded circumferential distance between any two adjacent distal bends 62 (or proximal bends 60) is defined as (s).

In general, the diameter W of each proximal bend 60 or distal bend 62 is within the range of from about 0.009 inches to about 0.070 inches depending upon the wire diameter. Diameter W is preferably as small as possible for a given wire diameter and wire characteristics. As will be appreciated by those of skill in the art, as the distance W is reduced to approach two times the cross-section of the wire, the bend 60 or 62 will exceed the elastic limit of the wire, and radial strength of the finished segment will be lost. Determination of a minimum value for W, in the context of a particular wire diameter and wire material, can be readily determined through routine experimentation by those of skill in the art.

As will be appreciated from Fig. 3 and 4, the sum of the distances (s) in a plane transverse to the longitudinal axis of the finished graft will correspond to the circumference of the finished graft cage in that plane. For a given circumference, the number of proximal bends 60 or distal bends 62 is directly related to the distance (s) in the corresponding plane. Preferably, the finished graft in any single transverse plane will have from about 3 to about 10 (s) dimensions, preferably from about 4 to about 8 (s) dimensions and, more preferably, about 5 or 6 (s) dimensions for an aortic application. Each (s) dimension corresponds to the distance between any two adjacent bends 60-60 or 62-62 as will be apparent from the discussion herein. Each segment 54 can thus be visualized as a series of triangles extending circumferentially around the axis of the graft, defined by a proximal bend 60 and two distal bends 62 or the reverse.

In one embodiment of the type illustrated in Fig. 4, w is about 2.0 mm 1 mm for a 0.018 inch wire diameter. D1 is about 3 mm 1 mm, and d is about 20 mm 1 mm. Specific dimensions for all of the foregoing variables can be varied considerably, depending upon the desired wire configuration, in view of the disclosure herein.

In one embodiment of the present invention, the apexes of adjacent segments are joined by an integral linkage formed from the wire. The form of the linkage may vary as detailed below including various types of interlocking junctions. In other embodiments, the apexes may be joined by independent structural elements such as sutures and wire

loops. In yet other embodiments, the apexes of adjacent segments may not be joined at all. Rather, the formed wire may be embedded in a polymeric membrane which acts both as the graft sleeve and as a means of joining adjacent segments. Such a design has the advantage that the profile of the stent graft may be very low, since no overlapping, interlocking or external junctions are employed to hold the wire segments together. Each of these variations is discussed below.

Referring to Fig.'s 5 and 6, one or more apexes 76 is provided with an elongated axial length d2, which permits the apex 76 to be wrapped around a corresponding portion 78 such as an apex of the adjacent segment to provide an interlocking link 70 between two axially adjacent cage segments. In one embodiment of the link 70 produced by the opposing apexes 76 and 78 of Fig. 6, utilizing wire having a diameter from .012" to .018", d1 is generally within the range of from about 1 mm to about 4 mm and d2 is within the range of from about 5 mm to about 9 mm. In general, a longer d2 dimension permits accommodation for greater axial travel of apex 78 with respect to 76, as will be discussed, thereby permitting greater lateral flexibility of the graft. W1 is within the range of from about 3 mm to about 5 mm, and W2 is sufficiently less than W1 that the apex 76 can fit within the apex 78. Any of a wide variety of specific apex configurations and dimensions can be utilized, as will be apparent to those of skill in the art in view of the disclosure herein. Regardless of the specific dimensions, the end of the apex 76 is advanced through the apex 78, and folded back upon its self to hook the apex 78 therein to provide a link 70 in accordance with the present invention.

The resulting link 70 (see Fig.'s 7 and 8) comprises a wall portion 71 extending in a first direction, substantially parallel to the axis of the graft, and a transverse portion 72 extending transverse to the axis of the graft. A return portion 73 extends generally in the opposite direction from the wall portion 71 to create a generally "U" shaped hook. In certain embodiments, a closing portion 74 is also provided, to minimize the risk of excessive axial compression of the wire cage. The forgoing structure produces a functionally closed aperture 77, which receives the interlocking section 75 of the adjacent graft segment. Alternatively, see Fig. 10.

In general, the aperture 77 preferably has a width (as viewed in Fig. 8) in the radial graft direction of substantially equal to the radial direction dimension of the interlocking section 75. In this embodiment, the interlocking section 75, as well as the locking portion 71 and return portion 73 can be flattened in the radial direction, to minimize the transverse cross-section of the link 70. In the axial direction, the aperture 77 is preferably greater than the axial direction dimension of the interlocking section 75, to accommodate some axial movement of each adjoining tubular segment of the graft. The axial length of the aperture 77 is at least about 2 times, and preferably at least about 3 or 4 times the cross-section of the interlocking section 75. The optimum axial length of the aperture 77 can be determined through routine experimentation by one of skill in the art in view of the intended clinical performance, taking into account the number of links 70 per transverse plane as well as the desired curvature of the finished graft.

Fig.'s 6A, 7A and 8A illustrate an alternate configuration for the moveable link 70. With this configuration, the radial expansion force will be higher.

Fig.'s 7B and 8B illustrate another alternate configuration. This linkage has a better resistance to axial compression and disengagement. Referring to Fig.'s 7B and 8B, the apex extends beyond closing portion 74 and into an axial portion 79 which extends generally parallel to the longitudinal axis of the graft. Provision of an axial extension 79

provides a more secure enclosure for the aperture 77 as will be apparent to those of skill in the art. The embodiments of Fig.'s 7B and 8B also illustrate an enclosed aperture 83 on the opposing apex. The aperture 83 is formed by wrapping the apex in at least one complete revolution so that a generally circumferentially extending portion 81 is provided. Circumferential portion 81 provides a stop, to limit axial compressibility of the graft. The closed aperture 83 can be formed by winding the wire of the apex about a mandrel either in the direction illustrated in Fig. 7B, or the direction illustrated in Fig. 7C. The embodiment of Fig. 7C advantageously provided only a single wire thickness through the aperture 77, thereby minimizing the wall thickness of the graft. This is accomplished by moving the crossover point outside of the aperture 77, as will be apparent from Fig. 7C.

The link 70 in accordance with the present invention is preferably formed integrally with the wire which forms the cage of the endovascular prosthesis. Alternatively, link 70 may be constructed from a separate material which is secured to the wire cage such as by soldering, suture, wrapping or the like.

The axial direction of the link 70 may also be varied, depending upon the desired performance characteristics of the graft. For example, the distal tips 76 of each link 70 may all face the same direction, such as proximal or distal with respect to the graft. See, for example, Fig. 5. Alternatively, one or more links in a given transverse plane of apexes may face in a proximal direction, and one or more links in the same transverse plane may face in the opposite direction. See, for example, Fig. 9.

Regardless of the axial orientation of the link 70, at least one and preferably at least two links 70 are provided per transverse plane separating adjacent graft segments. In an embodiment having six apexes per transverse plane, preferably at least two or three and in one embodiment all six opposing apex pairs are provided with a link 70. See Fig. 5.

The distribution of the interlocking link 70 throughout the wire cage can thus vary widely, depending upon the desired performance characteristics. For example, each opposing apex pair between adjacent tubular segments can be provided with a link 70. See Fig. 5. Alternatively, interlocking links 70 may be spaced circumferentially apart around the graft wall such as by positioning them at every second or third opposing apex pair.

The distribution of the links 70 may also be varied along the axial length of the graft. For example, a first zone at a proximal end of the graft and a second zone at a distal end of the graft may be provided with a relatively larger number of links 70 than a third zone in the central portion of the graft. In one embodiment, the transverse apex plane between the first and second tubular segments at the proximal end of the graft may be provided with a link 70 at each opposing apex pair. This has been determined by the present inventors to increase the radial strength of the graft, which may be desirable at the proximal (superior) end of the graft and possibly also at the distal end of the graft where resistance to leakage is an issue. A relatively lesser radial strength may be necessary in the central portion of the graft, where maintaining patency of the lumen is the primary concern. For this reason, relatively fewer links 70 may be utilized in a central zone, in an effort to simplify graft design as well as reduce collapse profile of the graft. See Fig. 12.

In one straight segment graft, having four graft segments, three transverse apex planes are provided. In the proximal apex plane, each opposing pair of apexes is provided with a link 70. In the central transverse apex plane, three of the six apex pairs are provided with a links 70, spaced apart at approximately 120°. Substantially equal circumferential

spacing of the link 70 is preferred, to provide relatively uniform resistance to bending regardless of graft position. The distal transverse apex plane may also be provided with a link 70 at each opposing apex pair.

The foregoing interlocking link 70 in accordance with the present invention can be readily adapted to both the straight segment grafts as discussed above, as well as to the bifurcated grafts discussed below.

The interlocking link 70 can be utilized to connect any of a number of independent graft segments in axial alignment to produce either a straight segment or a bifurcation graft. The interlocking link 70 may be utilized as the sole means of securing adjacent segments to each other, or may be supplemented by additional attachment structures such as metal loops, sutures, welds and others which are well understood in the art.

Referring to Fig.'s 12A through 12C there is illustrated a further wire layout which allows a smaller collapsed profile for the vascular graft. In general, the embodiment of Fig.'s 12A through 12C permits a series of links 70A and 70B to be staggered axially from one another as seen in Fig.'s 12A and 12B. In this manner, adjacent links 70 do not lie in the same transverse plane, and permit a tighter nesting of the collapsed wire cage. Preferably, between each adjoining graft segment, at least a first group of links 70A is offset axially from a second group of links 70B. In a six apex graft, having a link 70 at each apex, for example, a first group of every other apex 70A may be positioned slightly proximally of a second group of every other apex 70B. Referring to Fig. 12C, this may be accomplished by extending an apex 76A by a d3 distance which is at least about 1.2 times and as large as 1.5 times or 2 times or more the distance d2. The corresponding apexes 78 and 78A are similarly staggered axially, to produce the staggered interface between adjacent graft segments illustrated in Fig. 12A. Although a loop apex is illustrated in Fig. 12C as apex 78, any of the alternate apexes illustrated herein can be utilized in the staggered apex embodiment of the invention. The zig-zag pattern produced by axially offset links 70A and 70B can reside in a pair of parallel transverse planes extending generally between adjacent segments of the graft. Alternatively, the zig-zag relationship between adjacent links 70A and 70B can spiral around the circumference of a graft in a helical pattern, as will be understood by those of skill in the art in view of the disclosure herein. The precise axial offset between adjacent staggered links 70A and 70B can be optimized by one of ordinary skill in the art through routine experimentation, taking into account the desired physical properties and collapsed profile of the graft.

An alternative, low profile linkage between adjacent segments may be provided by the polymeric sleeve or membrane. In this embodiment, any of the variations of the wire cage illustrated and described with respect to Fig.'s 3 – 12C, may be coated on the inside, the outside, or preferably, on both the inside and the outside, by a polymeric sleeve, preferably of a laminated structure, which creates a flexible polymeric linkage of very low profile. In a preferred embodiment, where the wire cage is embedded between inner and outer layer(s) of polymeric material, the inner layer(s) may be adhered to the outer layer(s) through the openings between the adjacent wires of the support. The various mechanical linkages between adjacent segments of previously disclosed embodiments may be reduced in number or omitted when the embedding technology described below is used. Instead the ePTFE layer retains the desired spatial relationship between adjacent graft segments.

The sleeve or membrane that is used to cover the tubular wire graft cage can be manufactured from any of a variety of synthetic polymeric materials, or combinations thereof, including DACRON®, polyester, polyethylene, polypropylene, fluoropolymers, polyurethane foamed films, silicon, nylon, silk, thin sheets of super-elastic materials, woven materials, polyethylene terephthalate (PET), or any other biocompatible material. In one embodiment of the present invention, the membrane material is a fluoropolymer, in particular, expanded polytetrafluoroethylene (ePTFE) having a node-fibril structure. The ePTFE membrane used in the present invention is manufactured from thin films of ePTFE that are each approximately 0.0025 to 0.025 mm in thickness. Thus, the films could be 0.0025, 0.0050, 0.0075, 0.0100, 0.0125, 0.0150, 0.0175, 0.0200, 0.0225, and 0.0250 mm thick.

From 1 to about 200 plies (layers) of ePTFE film may be stacked up and laminated to one another to obtain a membrane with the desired mechanical and structural properties. An even number of layers are preferably stacked together (e.g., 2, 4, 6, 8, 10, etc.), with approximately 2 to 20 layers being desirable. Cross-lamination occurs by placing superimposed sheets on one another such that the film drawing direction, or stretching direction, of each sheet is angularly offset by angles between 0 degrees and 180 degrees from adjacent layers or plies. Because the base ePTFE is thin, as thin as 0.0025 mm thick, superimposed films can be rotated relative to one another to improve mechanical properties of the membrane. In one preferred embodiment, the membrane is manufactured by laminating between 4 to 8 plies of ePTFE film, each film ply being about 0.0125 mm thick.

In this embodiment, the membrane is made by laminating 4 plies of ePTFE film, each film being about 0.0125 mm thick. The laminated ePTFE sheets are then sintered together at temperatures of about 370° C, under vacuum to adhere the film layers to one another. The resultant 8-ply laminate structure is typically 0.0375 mm thick. Additional details and variations on the ePTFE laminating technology are disclosed in U.S. Patent No. 5,925,075 to Myers et al. the disclosure of which is herein incorporated in its entirety by reference thereto.

Any of the variations of formed wire configurations disclosed herein, particularly those described with reference to Fig. 13A-C, may be coated on the lumenal (inner) and/or external surface, or embedded within a laminated ePTFE membrane in accordance with the present invention. For example, as shown in Fig. 13A, separate zig-zag segments, similar to those illustrated in Fig. 3, but lacking the connector 66, may be assembled at a substantially fixed axial distance from one another by embedding in a ePTFE membrane. In the Fig. 13A variation the proximal bends 60 from one segment align with the distal bends 62 from the adjacent segment. Thus, the axial distance formed by two adjacent segments is greater than or equal to the sum of the axial length of each individual segment.

In another variation, shown in Fig. 13B, the separate zig-zag segments are rotationally offset and adjacent segments may be either spaced axially apart from each other or nested within adjacent segments, wherein each proximal bend 60 from a distal segment lies within angle α between two distal bends 62 of a proximal segment. In this embodiment, the axial length formed by two adjacent segments is less than the sum of the axial length of each individual segment. This design may be beneficial in applications where greater radial support is desired.

An alternative design is illustrated in Fig. 13C. In this variation of the wire support, a single length of wire is formed into a zig-zag pattern which is adapted to be rolled to form a spiral configuration, such as disclosed by An et

al., U.S. Patent No. 5,545,211, which is herein incorporated in its entirety by reference thereto. Unlike An, however, axially adjacent apexes in the wire support do not need to be interlinked. Thus, the present embodiment may be constructed without interlinking axially adjacent apexes as disclosed, for example, in U.S. Patent No. 5,217,483 to Tower, the disclosure of which is incorporated in its entirety herein by reference. The resulting wire cage design is thus similar to that disclosed in U.S. Patent No. 5,665,115 to Cragg, the disclosure of which is incorporated in its entirety herein by reference, after deletion of the loop members 12. Deletion of loop members 12 from the Cragg design is enabled by embedding the wire cage of the present invention in the multi-layer ePTFE or other polymeric membrane as disclosed herein.

EXAMPLE 1

A Nitinol wire cage (See e.g., Fig.'s 1-3, 13A-C) is provided with both a lumenal (inner) covering and an exterior covering of ePTFE film. The lumenal and exterior coverings are both made from a uniaxially-oriented film having fibrils oriented substantially in a single direction wherein the fibrils are all substantially parallel to each other. The lumenal covering is provided with the fibrils oriented parallel to the longitudinal axis of the tubular stent; the exterior covering is provided with the fibrils oriented substantially circumferential to the tubular stent. The film used for both the lumenal and exterior coverings is a porous ePTFE film having a discontinuous, porous coating of a fluoroethylene polymer (FEP) adhesive applied to one side of the porous ePTFE film. Examination of the FEP coated side of the film by scanning electron microscopy reveals FEP on only small portions of the nodes and fibrils at the surface of the film. It is estimated that less than 10% of the available node and fibril surface area exposed at the surface of the film are covered by FEP. The presence of the FEP adhesive thus has little or no adverse effect on the porosity of the porous ePTFE film.

The FEP-coated porous ePTFE film is made by a process which comprises the steps of:

a) contacting a porous ePTFE film with another layer which is preferably a film of FEP or alternatively of another thermoplastic polymer;

b) heating the composition obtained in step a) to a temperature above the melting point of the thermoplastic polymer;

c) stretching the heated composition of step b) while maintaining the temperature above the melting point of the thermoplastic polymer; and

d) cooling the product of step c).

In addition to FEP, other thermoplastic polymers including thermoplastic fluoropolymers may also be used to make this coated film. The adhesive coating on the porous ePTFE film may be either continuous (non-porous) or discontinuous (porous) depending primarily on the amount and rate of stretching, the temperature during stretching, and the thickness of the adhesive prior to stretching.

The discontinuously FEP-coated porous ePTFE film used to construct this example is of about 0.01 mm thickness and has a density of about 0.3 g/cc. The microstructure of the porous ePTFE contains fibrils of about 50 micron mean fibril length.

A length of film approximately equal to the length of the support cage to be covered and having uniaxially-oriented fibrils is wrapped as a single layer around a hollow, tubular, 1.5 cm outside diameter mandrel of non-porous PTFE to form a seam. The seam edges overlap by about 3 mm. The fibrils of the film are oriented parallel to the longitudinal axis of the mandrel; the FEP-coated side of the film faces away from the surface of the mandrel. The wire support is carefully fitted over the film-wrapped portion of the mandrel. The length of the wire support is centered over the length of the film-wrapped mandrel. The wire support is then provided with an exterior covering of a tape of the film described above by wrapping the tape circumferentially around the exterior surface of the mandrel so that the edges of the circumferentially-wrapped tape overlap by about 3 mm to form the seam. The circumferentially wrapped covering is oriented so that the FEP-coated side of the tape faces inward in contact with the exterior surface of the wire support and the outward facing FEP-coated surface of the lumenal layer of film is exposed through the openings in the wire support. Except for the overlapped seam edges, the circumferentially-wrapped covering is only one film layer thick. The uniaxially-oriented fibrils of the microstructure of the circumferentially-wrapped tape are circumferentially-oriented about the exterior wire support surface.

The film-wrapped mandrel assembly is placed into an oven set at 360° C for a period of 4 minutes after which the film-wrapped mandrel is removed from the oven and allowed to cool. Following cooling to approximately ambient temperature, the mandrel is removed from the film-wrapped wire support. The amount of heat applied is adequate to melt the FEP-coating on the porous ePTFE film and thereby cause adjacent layers of film to adhere to each other. Thus the lumenal layer of film is adhered to the exterior circumferentially wrapped layer through the openings between the adjacent wires of the support. The combined thickness of the lumenal and exterior coverings is about 0.025 mm.

EXAMPLE 2

A stainless steel wire support of the type illustrated in Figure 1 of the '115 to Cragg but without loop members 12 and dimensioned for use in the human abdominal aorta is provided with a lumenal covering of a porous ePTFE film having a microstructure of biaxially-oriented fibrils. This is accomplished by wrapping a hollow tubular mandrel of non-porous PTFE with a layer of porous ePTFE film having a continuous (non-porous) coating of FEP with the FEP-coated side of the film facing outwardly away from the mandrel surface. This film is about 0.02 mm thick; the porous ePTFE has a microstructure of uniaxially-oriented fibrils with the fibrils oriented circumferentially about the exterior surface of the mandrel. The wire support is carefully fitted over the film-wrapped portion of the mandrel. The mandrel assembly is then placed into an oven set at 360° C for four minutes. After removal from the oven and subsequent cooling, the mandrel is removed from the support leaving the wrapped film adhered to the lumenal surface of the support. This film is then peeled from the lumenal support surface leaving the FEP-coating and some small shreds of residual porous ePTFE adhered to the lumenal surface of the support wires. By removing the film and leaving the FEP adhesive on the lumenal stent surface, the film serves only as a release substrate for the application of the adhesive to the support surface.

The mandrel is then provided with a single layer wrapping of a porous ePTFE film having a microstructure of biaxially-oriented fibrils. This film is of about 30 micron fibril length, about 0.08 mm thickness, about 0.3 g/cc density and does not have an FEP coating. The biaxially-oriented fibrils are oriented to be substantially parallel to the longitudinal axis of the mandrel and to the circumference of the mandrel.

The film is overlapped adequately to form a 2 mm wide, longitudinally oriented seamline parallel to the longitudinal axis of the mandrel. A sheet of polyamide film was temporarily placed over the surface of the seam and then connected with the surface of a hand-held iron set at 400° C to cause the PTFE film seam edges to adhere to each other. Excess material beyond the 2 mm wide seam is trimmed away and discarded. The support is again carefully fitted over the film-covered mandrel. The resulting assembly is placed into an oven set at 380° C for three minutes and then removed and allowed to cool, after which the mandrel is removed from the support. The porous ePTFE film appears to be well adhered to the lumenal surface of the wire support by the FEP coating left from the first, previously removed, layer of film. The wall thickness of the PTFE film covering is about 0.08 mm.

EXAMPLE 3

A self expandable Nitinol wire support (e.g., Fig.'s 13A-13C) is adjusted from its collapsed outside diameter to an enlarged outside diameter by inserting a tapered stainless steel mandrel followed by a straight stainless steel mandrel. This support is then provided with a single layer exterior wrapping of the same discontinuously FEP-coated porous ePTFE coating used for the exterior wrapping of the support of Example 1. This is accomplished by wrapping the film about the exterior surface of the mandrel with the uniaxially-oriented fibrils of the film microstructure oriented parallel to the longitudinal axis of the support. This exterior covering is described as follows. A 2 mm wide seam is formed from the overlapped edges of the porous ePTFE film by temporarily placing a thin sheet of polyamide film over these edges and applying heat from a hand-held iron with a surface temperature of about 400° C. The film-wrapped support is then placed into an oven set at 380° C for 3 minutes, after which it is removed and allowed to cool. The film appears to be well adhered to the exterior surface of the support. The wall thickness of the film covering is about 0.01 mm. The enlarged support is then collapsed by the following process.

A series of 20 cm long 6-0 sutures are tied individually to each of the closed metal support openings adjacent to one end of the support. The film-covered support is provided with a temporary non-adhered additional wrapping of longitudinally-oriented film without FEP and having a microstructure of uniaxially-oriented fibrils. This temporary wrapping is intended as a dry lubricant. The enlarged support is then pulled by these sutures through a tapered die of round cross section and 2.5 cm length, the die having a tapered orifice with a 9.5 mm diameter bore at its entrance and a 4.5 mm diameter bore at its exit. The result is that the support is collapsed back to an outside diameter of 4.5 mm. The lubricity of the temporary covering of porous ePTFE film aids in making it possible to pull the support through the die. This temporary covering is removed after completion of the collapsing process. It is anticipated that the use of a tapered die having an approximately sized, smaller diameter exit bore would result in collapsing the support to its original collapsed diameter. The film-covered support is again enlarged to a diameter of 8 mm using a balloon catheter

followed by a tapered stainless steel mandrel. The covering of porous ePTFE film appears to be fully intact after the collapsing and enlarging of the film-covered stent.

Support coverings may be affixed to a support surface by variations on this method. For example, a tubular sleeve may be made from a film of porous ePTFE and inverted back into itself and fitted over the inner and outer surfaces of a support. The inner and outer portions of the tubular sleeve may be thermally adhered to each other through the openings in the support wall, or may be adhered to the support surfaces by an adhesive such as FEP, or may be affixed to the support by suturing the open ends of the tube together.

EXAMPLE 4

A formed wire (see e.g., Fig. 3 and Fig.'s 13A-C) made of Nitinol or any memory alloy may be constrained in a jig in its expanded layout and placed together with the jig into an oven, heated for at least two minutes, up to about one-half hour, at about 400° C to 600° C, e.g., 500° C, as described in U.S. Patent No. 5,879,366 to Shaw et al., which is herein incorporated in its entirety by reference thereto. The wire is cooled by air, water or any other means, and removed from the restraining jig. As the result of heating for 30 minutes at 500° C, the Nitinol wire obtains a "memory" for the particular configuration, which in this case is the enlarged tubular cage. Therefore, the wire exhibits super-elastic properties, which act to return the wire to the larger diameter tube even after extreme deformation, such as being collapsed within the delivery catheter. This memory-induced formed wire is then coated with one or more polymeric layers. The steps of coating the wire may occur either before the formed wire has been rolled into a tubular stent, or after the tubular stent has been formed.

The wire is coated with a bonding agent, for example FEP or other suitable thermoplastic polymer. If the wire is pre-rolled into a tube, a close tolerance FEP tube is slipped over the wire, so that the ends of the FEP tube are offset from the wire termination point. The FEP will then be heated and adhered to the wire during subsequent processing. The FEP coating can also be applied directly to the formed wire before rolling. Besides contacting the wire with a layer of FEP, the FEP coating may alternatively be applied by dipping, spraying, laminating between sheets, or any other means known in the art.

In one preferred method of applying an ePTFE membrane to a tubular, formed wire, a four-ply laminate is prepared from four tubular film layers (plies) of ePTFE. The film layers are placed onto a porous vacuum chuck with each film layer being rotated 90 degrees relative to one another.

One or more FEP coated formed wire structures are placed onto the four-ply laminate. Four additional layers of ePTFE film, rotated 90 degrees relative to each other, are placed onto the assembly, forming a second four-ply laminate structure, with the FEP coated wire structure(s) embedded between the two four-ply laminates.

This entire assembly is then covered with a Kapton tube or other high temperature plastic and placed into a sintering press. The sintering press applies vacuum through the porous vacuum chuck to the assembly. Sintering is conducted at temperatures of about 370° C for a period of several minutes, e.g., 15 minutes, up to several hours. The sintered assembly is cooled and the Kapton tube is removed and discarded.

Regardless of the particular configuration of wire cage (see e.g., Fig. 3 and Fig.'s 13A-C), where the wire is embedded in a polymeric sleeve or membrane, a cross section of the embedded support can be appreciated with reference to Fig. 14. Here, the wire 47 has a thin coating 48, which comprises a thermoplastic polymer adhesive, such as for example, FEP, described above. The coated wire is embedded within at least two layers of polymer film 20, such as for example, ePTFE, one each on the lumenal (inner) 30 and exterior 31 surfaces. The embedded support depicted in Fig. 14 is shown having two plies on each of the lumenal and external surfaces. As detailed above, however, preferably an even number of layers are stacked together (e.g., 2, 4, 6, 8, 10, etc.), with approximately 2 to 20 layers being desirable. Cross-lamination of superimposed sheets, angularly offset by angles between 0 degrees and 180 degrees from adjacent layers, is desired in order to improve mechanical properties of the membrane. As discussed in more detail above, the membrane is preferably manufactured by laminating between 4 to 8 plies of ePTFE film, each film ply being about 0.0125 mm thick. The laminated ePTFE sheets, fused together at temperatures of about 370° C under vacuum, form a low profile, flexible linkage between adjacent segments of the wire cage.

Other graft configurations and methods of coating wire stents with uniaxially and/or biaxially oriented ePTFE are encompassed by the present invention. One such alternate method is disclosed in U.S. Patent No. 5,788,626 to Thompson, which is herein incorporated in its entirety by reference thereto.

Another preferred embodiment of the present invention may be appreciated with reference to Fig.'s 15 A-C. In Fig. 15A, a two segment portion of the wire cage is shown in which the proximal 60 and distal 62 apexes from adjacent segments of the tubular member are aligned in the longitudinal axis, thereby essentially abutting one another as illustrated. In this variation, the wire cage is surrounded by a polymeric sleeve 44, preferably at least two ePTFE membranes, one along the lumenal surface and one along the exterior surface of the stent. The membranes may comprises any number of plies as discussed above. Alternatively, both surfaces of the cage may be covered by a single tube of ePTFE membrane (1-200 plys) extending through and folded over the wire cage resulting in a layer of ePTFE along both the lumenal and exterior surfaces. In either case, the PTFE envelope is spot welded in a pattern such as that shown in Fig. 15A, wherein the lumenal and exterior membranes are heat-fused in a plurality of spots 101. By spot-welding along the proximal and distal edges of the tubular member, the sleeve is closed around the support. Further, the pattern of four welding spots surrounding each apical junction, acts as a flexible linkage, thereby limiting movement of adjacent segments relative to one another. In areas of the graft in between the welding spots, the lumenal and exterior membranes are not necessarily fused.

As shown in end elevation from the distal margin of the graft (along line C-C) in Fig. 15C, the inner 30 and outer 31 membranes are fused at the welding spots 101, whereas the membrane layers can separate in between the welding spots. The sleeve is also illustrated surrounding the wire apexes 62. This design, like the previous variations in which the lumenal and exterior membranes were fused in all areas between adjacent wires, presents a very low profile, since the thickness of the PTFE membranes can be very small, as detailed above.

An alternative configuration is illustrated in Fig. 15B, wherein axially adjacent apexes of the support cage are circumferentially offset, such that distal apexes 62 from the adjacent segments are aligned with one another in the

longitudinal axis (and proximal apexes 60 from adjacent segments are aligned with one another in the longitudinal axis). In this embodiment, the distal apex 62 from a proximal segment is oriented between two adjacent proximal apexes 60 of the distal segment. As in Fig. 15A, the tubular wire segments are surrounded on both sides by a polymeric sleeve 44. An identical pattern of welding spots 101 is used to fasten the inner and outer membranes at the axial ends of the tubular member. Thus, the thin end elevation wall profile (shown in Fig. 15C) for the graft variation shown in Fig. 15B would be the same as that presented by the graft of Fig. 15A. However, along the length of the graft, at the junctions between adjacent tubular wire segments, the pattern of welding spots is different than that shown in Fig. 15B. In the inside angle of each apex, the membranes are spot welded. Further, in a preferred variation, at least alternating distal and proximal apexes and preferably all apexes may be surrounded by several spot welds. The precise pattern is not critical as long as the spot welds serve the purpose of securing the inner and outer polymer layers together and minimizing movement between adjacent segments in the longitudinal (or axial) direction.

The spot welding of the two membrane layers may be accomplished by any spot heating means known in the art. For example, a pointed heating iron, like a conventional soldering iron, could be used as long as it was adapted to maintain a membrane temperature sufficient to bond the layers of polymer film together. Typically for ePTFE, a temperature of 370° for about 15 minutes would be sufficient to fuse the layers together. In one preferred method of spot welding the lumenal and exterior PTFE membranes, an RF chamber may be programmed to make all of the necessary welds at once.

In one preferred embodiment of the invention, the material of ePTFE membrane or sleeve is sufficiently porous to permit ingrowth of endothelial cells, thereby providing more secure anchorage of the prosthesis and potentially reducing flow resistance, sheer forces, and leakage of blood around the prosthesis. Porosity in polymeric sleeve materials may be estimated by measuring water permeability as a function of hydrostatic pressure, which will preferably range from about 3 to 6 psi.

The porosity characteristics of the polymeric sleeve may be either homogeneous throughout the axial length of the prosthesis, or may vary according to the axial position along the prosthesis. For example, referring to Fig.'s 1 and 2, different physical properties will be called upon at different axial positions along the prosthesis 42 in use. At least a proximal portion 55 and a distal portion 59 of the prosthesis 42 will seat against the native vessel wall, proximally and distally of the aneurysm. In these proximal and distal portions, the prosthesis preferably encourages endothelial growth, or, at least, permits endothelial growth to infiltrate portions of the prosthesis in order to enhance anchoring and minimize leakage. A central portion 57 of the prosthesis spans the aneurysm, and anchoring is less of an issue. Instead, maximizing lumen diameter and minimizing blood flow through the prosthesis wall become primary objectives. Thus, in a central zone 57 of the prosthesis 42, the polymeric membrane or sleeve 44 may either be nonporous, or provided with pores of relatively lower porosity

A multi-zoned prosthesis 42 may also be provided in accordance with the present invention by positioning a tubular sleeve 44 on a central portion 57 of the prosthesis, such that it spans the aneurysm to be treated, but leaving a proximal attachment zone 55 and a distal attachment zone 59 of the prosthesis 42 having exposed wires from the wire

support 46. In this embodiment, the exposed wires 46 are positioned in contact with the vessel wall both proximally and distally of the aneurysm, such that the wire, over time, may become embedded in cell growth on the interior surface of the vessel wall.

In one embodiment of the prosthesis 42, the sleeve 44 and/or the wire support 46 is tapered, having a relatively larger expanded diameter at the proximal end 50 compared to the distal end 52. The tapered design may allow the prosthesis to conform better to the natural decreasing distal cross-section of the vessel, to reduce the risk of graft migration and potentially create better flow dynamics. The cage 46 can be provided with a proximal zone 55 and distal zone 59 that have a larger average expanded diameter than the central zone 57, as illustrated in Fig. 2. This configuration may desirably resist migration of the prosthesis within the vessel and reduce leakage around the ends of the prosthesis.

Referring to Fig.'s 16 and 17, a straight segment deployment device and method in accordance with a preferred embodiment of the present invention are illustrated. A delivery catheter 80, having a dilator tip 82, is advanced along guidewire 84 until the (anatomically) proximal end 50 of the collapsed endoluminal vascular prosthesis 88 is positioned between the renal arteries 32 and 34 and the aneurysm 40. The collapsed prosthesis in accordance with the present invention has a diameter in the range of about 2 to about 10 mm. Generally, the diameter of the collapsed prosthesis is in the range of about 3 to 6 mm (12 to 18 French). Preferably, the delivery catheter including the prosthesis will be 16 F, or 15 F or 14 F or smaller.

The prosthesis 88 is maintained in its collapsed configuration by the restraining walls of the tubular delivery catheter 80, such that removal of this restraint would allow the prosthesis to self expand. Radiopaque marker material may be incorporated into the delivery catheter 80, and/or the prosthesis 88, at least at both the proximal and distal ends, to facilitate monitoring of prosthesis position. The dilator tip 82 is bonded to an internal catheter core 92, as illustrated in Fig. 17, so that the internal catheter core 92 and the partially expanded prosthesis 88 are revealed as the outer sheath of the delivery catheter 80 is retracted.

As the outer sheath is retracted, the collapsed prosthesis 88 remains substantially fixed axially relative to the internal catheter core 92 and consequently, self-expands at a predetermined vascular site as illustrated in Fig. 17. Continued retraction of the outer sheath results in complete deployment of the graft. After deployment, the expanded endoluminal vascular prosthesis 88 has radially self-expanded to a diameter anywhere in the range of about 20 to 40 mm, corresponding to expansion ratios of about 1:2 to 1:20. In a preferred embodiment, the expansion ratios range from about 1:4 to 1:8, more preferably from about 1:4 to 1:6.

In addition to, or in place of, the outer sheath described above, the prosthesis 88 may be maintained in its collapsed configuration by a restraining lace, which may be woven through the prosthesis or wrapped around the outside of the prosthesis in the collapsed reduced diameter. Following placement of the prosthesis at the treatment site, the lace can be proximally retracted from the prosthesis thereby releasing it to self expand at the treatment site. The lace may comprise any of a variety of materials, such as sutures, strips of PTFE, FEP, polyester fiber, and others as will be apparent to those of skill in the art in view of the disclosure herein. The restraining lace may extend proximally through a lumen in the delivery catheter or outside of the catheter to a proximal control. The control may be a pull-tab or ring, rotatable reel,

slider switch or other structure for permitting proximal retraction of the lace. The lace may extend continuously throughout the length of the catheter, or may be joined to another axially moveable element such as a pull wire.

In general, the expanded diameter of the graft in accordance with the present invention can be any diameter useful for the intended lumen or hollow organ in which the graft is to be deployed. For most arterial vascular applications, the expanded size will be within the range of from about 10 to about 40 mm. Abdominal aortic applications will generally require a graft having an expanded diameter within the range of from about 20 to about 28 mm, and, for example, a graft on the order of about 45 mm may be useful in the thoracic artery. The foregoing dimensions refer to the expanded size of the graft in an unconstrained configuration, such as on the table. In general, the graft will be positioned within an artery having a slightly smaller interior cross-section than the expanded size of the graft. This enables the graft to maintain a slight positive pressure against the wall of the artery, to assist in retention of the graft during the period of time prior to endothelialization of the polymeric sleeve 44.

The radial force exerted by the proximal segment 94 of the prosthesis against the walls of the aorta 30 provides a seal against the leakage of blood around the vascular prosthesis and tends to prevent axial migration of the deployed prosthesis. As discussed above, this radial force can be modified as required through manipulation of various design parameters, including the axial length of the segment and the bend configurations. In another embodiment of the present invention, radial tension can be enhanced at the proximal, upstream end by increasing the wire gauge in the proximal zone. Wire diameter may range from about 0.001 to 0.01 inches in the distal region to a range of from about 0.01 to 0.03 inches in the proximal region.

An alternative embodiment of the wire layout which would cause the radial tension to progressively decrease from the proximal segments to the distal segments, involves a progressive or step-wise decrease in the wire gauge throughout the entire wire support, from about 0.01 to 0.03 inches at the proximal end to about 0.002 to 0.01 inches at the distal end. Such an embodiment, may be used to create a tapered prosthesis. Alternatively, the wire gauge may be thicker at both the proximal and distal ends, in order to insure greater radial tension and thus, sealing capacity. Thus, for instance, the wire gauge in the proximal and distal segments may about 0.01 to 0.03 inches, whereas the intervening segments may be constructed of thinner wire, in the range of about 0.001 to 0.01 inches.

Referring to Fig. 18, there is illustrated two alternative deployment sites for the endoluminal vascular prosthesis 42 of the present invention. For example, an aneurysm 33 is illustrated in the right renal artery 32. An expanded endoluminal vascular prosthesis 42, in accordance with the present invention, is illustrated spanning that aneurysm 33. Similarly, an aneurysm 37 of the right common iliac 36 is shown, with a prosthesis 42 deployed to span the iliac aneurysm 37.

Referring to Fig. 19, there is illustrated a modified embodiment of the endovascular prosthesis 96 in accordance with the present invention. In the embodiment illustrated in Fig. 19, the endovascular prosthesis 96 is provided with a wire cage 46 having six axially aligned segments 54. As with the previous embodiments, however, the endovascular prosthesis 96 may be provided with anywhere from about 2 to about 10 or more axially spaced or adjacent segments 54, depending upon the clinical performance objectives of the particular embodiment.

The wire support 46 is provided with a tubular polymeric sleeve 44 as has been discussed. In the present embodiment, however, one or more lateral perfusion ports or openings are provided in the polymeric sleeve 44, such as a right renal artery perfusion port 98 and a left renal artery perfusion port 100 as illustrated.

Perfusion ports in the polymeric sleeve 44 may be desirable in embodiments of the endovascular prosthesis 96 in a variety of clinical contexts. For example, although Fig.'s 1 and 19 illustrate a generally symmetrical aneurysm 40 positioned within a linear infrarenal portion of the abdominal aorta, spaced axially apart both from bilaterally symmetrical right and left renal arteries and bilaterally symmetrical right and left common iliacs, both the position and symmetry of the aneurysm 40 as well as the layout of the abdominal aortic architecture may differ significantly from patient to patient. As a consequence, the endovascular prosthesis 96 may need to extend across one or both of the renal arteries in order to adequately anchor the endovascular prosthesis 96 and/or span the aneurysm 40. The provision of one or more lateral perfusion ports or zones enables the endovascular prosthesis 96 to span the renal arteries while permitting perfusion therethrough, thereby preventing "stent jailing" of the renals. Lateral perfusion through the endovascular prosthesis 96 may also be provided, if desired, for a variety of other arteries including the second lumbar, testicular, inferior mesenteric, middle sacral, and alike as will be well understood to those of skill in the art.

The endovascular prosthesis 96 is preferably provided with at least one, and preferably two or more radiopaque markers, to facilitate proper positioning of the prosthesis 96 within the artery. In an embodiment having perfusion ports 98 and 100 such as in the illustrated design, the prosthesis 96 should be properly aligned both axially and rotationally, thereby requiring the ability to visualize both the axial and rotational position of the device. Alternatively, provided that the delivery catheter design exhibits sufficient torque transmission, the rotational orientation of the graft may be coordinated with an indexed marker on the proximal end of the catheter, so that the catheter may be rotated and determined by an external indicia of rotational orientation to be appropriately aligned with the right and left renal arteries.

In an alternative embodiment, the polymeric sleeve 44 extends across the aneurysm 40, but terminates in the infrarenal zone. In this embodiment, a proximal zone 55 on the prosthesis 96 comprises a wire cage 46 but no polymeric sleeve 44. In this embodiment, the prosthesis 96 still accomplishes the anchoring function across the renal arteries, yet does not materially interfere with renal perfusion. Thus, the polymeric sleeve 44 may cover anywhere from about 50% to about 100% of the axial length of the prosthesis 96 depending upon the desired length of uncovered wire cage 46 such as for anchoring and/or lateral perfusion purposes. In particular embodiments, the polymeric sleeve 44 may cover within the range of from about 70% to about 80%, and, in one four segment embodiment having a single exposed segment, 75%, of the overall length of the prosthesis 96. The uncovered wire cage 46 may reside at only a single end of the prosthesis 96, such as for traversing the renal arteries. Alternatively, exposed portions of the wire cage 46 may be provided at both ends of the prosthesis such as for anchoring purposes.

In a further alternative, a two part polymeric sleeve 44 is provided. A first distal part spans the aneurysm 40, and has a proximal end that terminates distally of the renal arteries. A second, proximal part of the polymeric sleeve 44 is carried by the proximal portion of the wire cage 46 that is positioned superiorly of the renal arteries. This leaves an

annular lateral flow path through the side wall of the vascular prosthesis 96, which can be axially aligned with the renal arteries, without regard to rotational orientation.

The axial length of the gap between the proximal and distal segments of polymeric sleeve 44 can be adjusted, depending upon the anticipated cross-sectional size of the ostium of the renal artery, as well as the potential axial misalignment between the right and left renal arteries. Although the right renal artery 32 and left renal artery 34 are illustrated in Fig. 19 as being concentrically disposed on opposite sides of the abdominal aorta, the take off point for the right or left renal arteries from the abdominal aorta may be spaced apart along the abdominal aorta as will be familiar to those of skill in the art. In general, the diameter of the ostium of the renal artery measured in the axial direction along the abdominal aorta falls within the range of from about 7 mm to about 20 mm for a typical adult patient.

Prior art procedures presently use a 7 mm introducer (18 French) which involves a surgical procedure for introduction of the graft delivery device. Embodiments of the present invention can be constructed having a 16 French or 15 French or 14 French or smaller profile (e.g. 3-4 mm) thereby enabling placement of the endoluminal vascular prosthesis of the present invention by way of a percutaneous procedure. In addition, the endoluminal vascular prosthesis of the present invention does not require a post implantation balloon dilatation, can be constructed to have minimal axial shrinkage upon radial expansion.

Referring to Fig. 20, there is disclosed a schematic representation of the abdominal part of the aorta and its principal branches as in Fig. 1. An expanded bifurcated endoluminal vascular prosthesis 102, in accordance with the present invention, is illustrated spanning the aneurysms 103, 104 and 105. The endoluminal vascular prosthesis 102 includes a polymeric sleeve 106 and a tubular wire support 107, which are illustrated *in situ* in Fig. 20. The sleeve 106 and wire support 107 are more readily visualized in the exploded view shown in Fig. 22. The endoluminal prosthesis 102 illustrated and described herein depicts an embodiment in which the polymeric sleeve 106 is situated concentrically outside of the tubular wire support 107. However, other embodiments may include a sleeve situated instead concentrically inside the wire support or on both of the inside and the outside of the wire support. Alternatively, the wire support may be embedded within a polymeric matrix which makes up the sleeve. Regardless of whether the sleeve 106 is inside or outside the wire support 107, the sleeve may be attached to the wire support by any of a variety of means, as has been previously discussed.

The tubular wire support 107 comprises a primary component 108 for traversing the aorta and a first iliac, and a branch component 109 for extending into the second iliac. The primary component 108 may be formed from a continuous single length of wire, throughout both the aorta trunk portion and the iliac branch portion. See Fig.'s 22 and 23. Alternatively, each iliac branch component can be formed separately from the aorta trunk portion. Construction of the graft from a three part cage conveniently facilitates the use of different gauge wire in the different components (e.g. 14 gauge main trunk and 10 gauge branch components).

The wire support 107 is preferably formed in a plurality of discrete segments, connected together and oriented about a common axis. In Fig. 23, Section A corresponds to the aorta trunk portion of the primary component 108, and includes segments 1-5. Segments 6-8 (Section B) correspond to the iliac branch portion of the primary component 108.

In general, each of the components of the tubular wire support 107 can be varied considerably in diameter, length, and expansion coefficient, depending upon the intended application. For implantation within a typical adult, the aorta trunk portion (section A) of primary component 108 will have a length within the range of from about 5 cm to about 12 cm, and, typically within the range of from about 9 cm to about 10 cm. The unconstrained outside expanded diameter of the section A portion of the primary component 108 will typically be within the range of from about 20 mm to about 40 mm. The unconstrained expanded outside diameter of the section A portion of primary component 108 can be constant or substantially constant throughout the length of section A, or can be tapered from a relatively larger diameter at the proximal end to a relatively smaller diameter at the bifurcation. In general, the diameter of the distal end of section A will be on the order of no more than about 95% and, preferably, no more than about 85% of the diameter of the proximal end of section A.

The right and left iliac portions, corresponding to section B on primary component 108 and section C will typically be bilaterally symmetrical. Section C length will generally be within the range of from about 1 cm to about 5 cm, and section C diameter will typically be within the range of from about 10 mm to about 20 mm.

Referring to Fig. 22, the wire cage 107 is dividable into a proximal zone 110, a central zone 111 and a distal zone 112. As has been discussed, the wire cage 107 can be configured to taper from a relatively larger diameter in the proximal zone 110 to a relatively smaller diameter in the distal zone 112. In addition, the wire cage 107 can have a transitional tapered and or stepped diameter within a given zone.

Referring to Fig. 23, there is illustrated a plan view of the single formed wire used for rolling about a longitudinal axis to produce a primary segment 108 having a five segment aorta section and a three segment iliac section. The formed wire exhibits distinct segments, each corresponding to an individual tubular segment in the tubular support. Additional details of the wire cage layout and construction can be found in co-pending United States patent application serial no. 09/034,689 entitled Endoluminal Vascular Prosthesis, filed March 4, 1998, the disclosure of which is incorporated in its entirety herein by reference.

Each segment has a repeating pattern of proximal bends 60 connected to corresponding distal bends 62 by wall sections 64 which extend in a generally zig-zag configuration when the segment is radially expanded, as has been discussed in connection with Fig. 3. Each segment is connected to the adjacent segment through a connector 66, and one or more links 70 as has been discussed in connection with Fig.'s 5-12. The connector 66 in the illustrated embodiment comprises two wall sections 64 which connect a proximal bend 60 on a first segment with a distal bend 62 on a second, adjacent segment. The connector 66 may additionally be provided with a connector bend 68, which may be used to impart increased radial strength to the graft and/or provide a tie site for a circumferentially extending suture.

In the illustrated embodiment, section A is intended for deployment within the aorta whereas section B is intended to be deployed within a first iliac. Thus, section B will preferably have a smaller expanded diameter than section A. This may be accomplished by providing fewer proximal and distal bends 60, 62 per segment in section B or in other manners as will be apparent to those of skill in the art in view of the disclosure herein. In the illustrated embodiment, section B has one fewer proximal bend 60 per segment than does each segment in section A. This facilitates wrapping of

the wire into a tubular prosthesis cage such as that illustrated in Fig. 22, so that the iliac branch has a smaller diameter than the aorta branch. At the bifurcation, an opening remains for connection of the second iliac branch. The second branch is preferably formed from a section of wire in accordance with the general principles discussed above, and in a manner that produces a similarly dimensioned wire cage as that produced by section B. The second iliac branch (section C) may be attached at the bifurcation to section A and/or section B in any of a variety of manners, to provide a secure junction therebetween. In one embodiment, one or two of the proximal bends 60 on section C will be secured to the corresponding distal bends 62 on the distal most segment of section A. Attachment may be accomplished such as through the use of a circumferentially threaded suture, through links 70 as has been discussed previously, through soldering or other attachment means. The attachment means will be influenced by the desirable flexibility of the graft at the bifurcation, which will in turn be influenced by the method of deployment of the vascular graft as will be apparent to those of skill in the art in view of the disclosure herein.

Referring to Fig. 24, there is disclosed an exploded schematic representation of a hinged or articulated variation in the tubular wire support structure for a bifurcated graft in accordance with present invention. The tubular wire support comprises a main body, or aortic trunk portion 200 and right 202 and left 204 iliac branch portions. Right and left designations correspond to the anatomic designations of right and left common iliac arteries. The proximal end 206 of the aortic trunk portion 200 has apexes 211-216 adapted for connection with the complementary apexes on the distal ends 208 and 210 of the right 202 and left 204 iliac branch portions, respectively. Complementary pairing of apexes is indicated by the shared numbers, wherein the right branch portion apexes are designated by (R) and the left branch portion apexes are designated by (L). Each of the portions may be formed from a continuous single length of wire. See Fig. 26.

Referring to Fig. 25, the assembled articulated wire support structure is shown. The central or medial apex 213 in the foreground (anterior) of the aortic trunk portion 200 is linked with 213(R) on the right iliac portion 202 and 213(L) on the left iliac portion 204. Similarly, the central apex 214 in the background (posterior) is linked with 214(R) on the right iliac portion 202 and 214(L) on the left iliac portion 204. Each of these linkages has two iliac apexes joined with one aortic branch apex. The linkage configurations may be of any of the variety described above in Fig. 7A-D. The medial most apexes 218 (R) and (L) of the iliac branch portions 202 and 204 are linked together, without direct connection with the aortic truck portion 200.

The medial apexes 213 and 214 function as pivot points about which the right and left iliac branches 202, 204 can pivot to accommodate unique anatomies. Although the right and left iliac branches 202, 204 are illustrated at an angle of about 45° to each other, they are articulable through at least an angle of about 90° and preferably at least about 120°. The illustrated embodiment allows articulation through about 180° while maintaining patency of the central lumen. To further improve patency at high iliac angles, the apexes 213 and 214 can be displaced proximally from the transverse plane which roughly contains apexes 211, 212, 215 and 216 by a minor adjustment to the fixture about which the wire is formed. Advancing the pivot point proximally relative to the lateral apexes (e.g., 211, 216) opens the unbiased angle between the iliac branches 202 and 204.

In the illustrated embodiment, the pivot point is formed by a moveable link between an eye on apex 213 and two apexes 213R and 213L folded therethrough. To accommodate the two iliac apexes 213R and 213L, the diameter of the eye at apex 213 may be slightly larger than the diameter of the eye on other apexes throughout the graft. Thus, for example, the diameter of the eye at apex 213 in one embodiment made from .014" diameter wire is about 0.059", compared to a diameter of about 0.020" for eyes elsewhere in the graft.

Although the pivot points (apexes 213, 214) in the illustrated embodiment are on the medial plane, they may be moved laterally such as, for example, to the axis of each of the iliac branches. In this variation, each iliac branch will have an anterior and a posterior pivot link on or about its longitudinal axis, for a total of four unique pivot links at the bifurcation. Alternatively, the pivot points can be moved as far as to lateral apexes 211 and 216. Other variations will be apparent to those of skill in the art in view of the disclosure herein.

To facilitate lateral rotation of the iliac branches 202, 204 about the pivot points and away from the longitudinal axis of the aorta trunk portion 200 of the graft, the remaining links between the aorta trunk portion 200 and the iliac branches 202, 204 preferably permit axial compression and expansion. In general, at least one and preferably several links lateral to the pivot point in the illustrated embodiment permit axial compression or shortening of the graft to accommodate lateral pivoting of the iliac branch. If the pivot point is moved laterally from the longitudinal axis of the aorta portion of the graft, any links medial of the pivot point preferably permit axial elongation to accommodate lateral rotation of the branch. In this manner, the desired range of rotation of the iliac branches may be accomplished with minimal deformation of the wire, and with patency of the graft optimized throughout the angular range of motion.

To permit axial compression substantially without deformation of the wire, the lateral linkages, 211 and 212 for the right iliac, and 215 and 216 for the left iliac, may be different from the previously described apex-to-apex linkage configurations. The lateral linkages are preferably slideable linkages, wherein a loop formed at the distal end of the iliac apex slideably engages a strut of the corresponding aortic truck portion. The loop and strut orientation may be reversed, as will be apparent to those of skill in the art. Interlocking "elbows" without any distinct loop may also be used. Such an axially compressible linkage on the lateral margins of the assembled wire support structure allow the iliac branch portions much greater lateral flexibility, thereby facilitating placement in patients who often exhibit a variety of iliac branch asymmetries and different angles of divergence from the aortic trunk.

Referring to Fig. 26, there is illustrated a plan view of a single formed wire used for rolling about a longitudinal axis to produce a four segment straight tubular wire support for an iliac limb. The formed wire exhibits distinct segments, each corresponding to an individual tubular segment in the tubular supports 202 or 204 (See Fig. 24). The distal segment I, is adapted to articulate with the aortic trunk portion 200 and the adjacent iliac limb portion. The distal segment (I) has two apexes (e.g. corresponding to 211 and 212 on the right iliac portion 202 in Fig. 23) which form a loop adapted to slideably engage a strut in the lateral wall of the aortic portion. These articulating loops (A) are enlarged in Fig. 27A. As discussed above, the loops are preferably looped around a strut on the corresponding apex of the proximal aortic segment to provide a sliding linkage.

The apex 218 is proximally displaced relative to the other four apexes in the distal segment (I). Apex 218 (R or L) is designed to link with the complementary 218 apex on the other iliac branch portion (See Fig. 25). The apex 218 in the illustrated embodiment is formed adjacent or near an intersegment connector 66, which extends proximally from the distal segment.

The other apexes on the distal segment (I) of an iliac limb are designed to link with a loop on the corresponding apex of the proximal aortic segment. Because many variations of this linkage are consistent with the present invention (See Fig.'s 7A-D), the form of the corresponding apexes may vary. In a preferred variation, the apexes (B) form a narrow U-shape, having an inside diameter of about 0.019 inches in an embodiment made from 0.012 inch Conichrome wire (tensile strength 300 ksi minimum) as illustrated in Fig. 27B. The U-shaped, elongated axial portion of the apex shown in Fig. 25B permits the apex to be wrapped through and around a corresponding loop apex of the proximal aortic segment. This type of linkage is discussed in greater detail above in connection with Fig.'s 5 and 6.

In more general terms, the wire support illustrated in Fig.'s 24 and 25 comprises a main body support structure formed from one or more lengths of wire and having a proximal end, a distal end and a central lumen extending along a longitudinal axis. The wire support also comprises a first branch support structure formed from one or more lengths of wire and having a proximal end, a distal end and a central lumen therethrough. The first branch support structure is pivotably connected to the proximal end of the main body support structure. The tubular wire support further comprises a second branch support structure formed from one or more lengths of wire and having a proximal end, a distal end and a central lumen extending therethrough. The distal end of the second branch support structure is pivotably connected to the proximal end of the main body support structure.

Further, the distal ends of the first and second branch structures may be joined together by a flexible linkage, formed for example between apexes 218(R) and 218(L) in Fig. 24. By incorporating a medial linkage between the two branch support structures and pivotable linkages with the main trunk, the first and second branch support structures can hinge laterally outward from the longitudinal axis without compromising the volume of the lumen. Thus, the branches may enjoy a wide range of lateral movement, thereby accommodating a variety of patient and vessel heterogeneity. Additional corresponding apexes between the main trunk and each iliac branch may also be connected, or may be free floating within the outer polymeric sleeve. Axially compressible lateral linkages, discussed above and illustrated in Fig. 25, may optionally be added.

The proximal apexes (C) of the iliac limb portions are adapted to link with the distal apexes of the next segment. These proximal apexes preferably form loops, such as those illustrated in Fig. 27C, wherein the elongated axial portions of the corresponding proximal apex in the adjacent segment can wrap around the loop, thereby providing flexibility of the graft, as discussed above for Fig.'s 5 and 6.

The wire may be made from any of a variety of different alloys and wire diameters or non-round cross-sections, as has been discussed. In one embodiment of the bifurcation graft, the wire gauge remains substantially constant throughout section A of the primary component 49 and steps down to a second, smaller cross-section throughout section B of primary component 108.

A wire diameter of approximately 0.018 inches may be useful in the aorta trunk portion of a graft having five segments each having 2.0 cm length per segment, each segment having six struts intended for use in the aorta, while a smaller diameter such as 0.012 inches might be useful for segments of the graft having 6 struts per segment intended for the iliac artery.

In one embodiment of the present invention, the wire diameter may be tapered throughout from the proximal to distal ends of the section A and/or section B portions of the primary component 108. Alternatively, the wire diameter may be tapered incremental or stepped down, or stepped up, depending on the radial strength requirements of each particular clinical application. In one embodiment, intended for the abdominal aortic artery, the wire has a cross-section of about 0.018 inches in the proximal zone 110 and the wire tapers down regularly or in one or more steps to a diameter of about 0.012 inches in the distal zone 112 of the graft 102. End point dimensions and rates of taper can be varied widely, within the spirit of the present invention, depending upon the desired clinical performance.

In general, in the tapered or stepped wire embodiments, the diameter of the wire in the iliac branches is no more than about 80% of the diameter of the wire in the aortic trunk. This permits increased flexibility of the graft in the region of the iliac branches, which has been determined by the present inventors to be clinically desirable.

The collapsed prosthesis in accordance with the present invention has a diameter in the range of about 2 to about 10 mm. Preferably, the maximum diameter of the collapsed prosthesis is in the range of about 3 to 6 mm (12 to 18 French). Some embodiments of the delivery catheter including the prosthesis will be in the range of from 18 to 20 or 21 French; other embodiments will be as low as 19 F, 16 F, 14 F, or smaller. After deployment, the expanded endoluminal vascular prosthesis has radially self-expanded to a diameter anywhere in the range of about 20 to 40 mm, corresponding to expansion ratios of about 1:2 to 1:20. In a preferred embodiment, the expansion ratios range from about 1:4 to 1:8, more preferably from about 1:4 to 1:6.

As described above in detail with respect to the linkage of stent segments using the polymeric sleeve, the same construction and methods are applicable to the flexible bifurcated wire cage just described. Thus, the bifurcated stent can be coated on the lumenal side, the external side, or preferably embedded within layers of porous, expandable polymeric material, as described above.

The self-expandable bifurcation graft of the present invention can be deployed at a treatment site in accordance with any of a variety of techniques as will be apparent to those of skill in the art. One such technique is disclosed in co-pending patent application serial No. 08/802,478 entitled Bifurcated Vascular Graft and Method and Apparatus for Deploying Same, filed February 20, 1997, the disclosure of which is incorporated in its entirety herein by reference.

While a number of preferred embodiments of the invention and variations thereof have been described in detail, other modifications and methods of using and medical applications for the same will be apparent to those of skill in the art. Accordingly, it should be understood that various applications, modifications, and substitutions may be made of equivalents without departing from the spirit of the invention or the scope of the claims.

WHAT IS CLAIMED IS:

1. An endoluminal prosthesis, comprising:

a tubular wire support with proximal and distal ends and a central lumen extending therebetween, and having a lumenal surface and an exterior surface, the wire support comprising at least two axially adjacent tubular segments, each segment comprising a series of proximal and distal bends connected by a length of wire, wherein the wire support is radially compressible into a first, reduced cross sectional configuration for implantation into a body lumen and self expandable to a second, enlarged cross sectional configuration at a treatment site in a body lumen; and

a membrane formed from at least one layer of a polymeric film and adhering to at least a portion of each adjacent segment of the wire support, wherein the membrane inhibits adjacent segments from moving axially relative to one another.

2. The endoluminal prosthesis of Claim 1, comprising at least three segments.

3. The endoluminal prosthesis of Claim 1, comprising at least five segments.

4. The endoluminal prosthesis of Claim 1, wherein each segment comprises from about 4 proximal bends to about 12 proximal bends.

5. The endoluminal prosthesis of Claim 1, wherein the polymeric film comprises expanded polytetrafluoroethylene (ePTFE).

6. The endoluminal prosthesis of Claim 5, wherein the at least one layer of ePTFE film has fibrils oriented substantially in a single direction.

7. The endoluminal prosthesis of Claim 6, wherein the membrane is formed from more than one layer of ePTFE film.

8. The endoluminal prosthesis of Claim 7, wherein the layers of ePTFE are cross-laminated such that the fibrils from one layer are angularly offset in relation to the fibrils from an adjacent layer.

9. The endoluminal prosthesis of Claim 8, wherein the cross-laminated layers of ePTFE film are offset at an angle of between 0 and 180°.

10. The endoluminal prosthesis of Claim 1, further comprising an adhesive for adhering the membrane to the wire support.

11. The endoluminal prosthesis of Claim 10, wherein the adhesive is a thermoplastic polymer adhesive.

12. The endoluminal prosthesis of Claim 11, wherein the thermoplastic polymer adhesive is fluoroethylene polymer (FEP).

13. The endoluminal prosthesis of Claim 1, wherein two membranes are bound to at least a portion of each adjacent segment, a first membrane along the lumenal surface and a second membrane along the exterior surface, such that the wire support is substantially embedded between the first and second membranes.

14. The endoluminal prosthesis of Claim 13, wherein the first membrane is at least partially adhered to the second membrane through openings between the wire support.

15. The endoluminal prosthesis of Claim 14, wherein each membrane is formed from an equal number of layers of ePTFE film.

16. The endoluminal prosthesis of Claim 15, wherein each membrane has between 2 and 20 layers of ePTFE film.

17. The endoluminal prosthesis of Claim 16, wherein each ePTFE film has fibrils oriented substantially in a single direction.

18. The endoluminal prosthesis of Claim 17, wherein the layers of ePTFE film which form each membrane are cross-laminated such that the fibrils from one layer are angularly offset in relation to the fibrils from an adjacent layer.

19. The endoluminal prosthesis of Claim 1, wherein two membrane layers cover at least a portion of each adjacent segment, a first membrane along the lumenal surface and a second membrane along the exterior surface, such that the wire support is substantially surrounded by the first and second membranes, and wherein the first membrane is adhered to the second membrane at a plurality of spots disposed around the proximal and distal bends in the wire support, such that the membrane inhibits adjacent segments from moving axially relative to one another.

20. A bifurcated endoluminal prosthesis, comprising:

a body graft tube and first and second branch graft tubes attached by a pivotable linkage to the body graft tube to form a y-shaped prosthesis, each tube comprising at least two axially adjacent tubular segments, each segment comprising a wire forming a series of proximal and distal bends; and

a membrane formed from at least one layer of a polymeric film and adhered to at least a portion of the adjacent tubular segments, wherein the membrane inhibits the adjacent segments from moving axially relative to one another.

21. A method of making an endoluminal prosthesis, comprising the steps of:

providing a length of wire;

forming the wire into at least two zig-zag segments;

rolling the formed wire about an axis to produce a tubular wire support comprising a series of tubular elements positioned along the axis, the tubular wire support having a lumenal surface and an exterior surface;

contacting an ePTFE membrane to each of the at least one surface of the tubular wire support;

heating the tubular wire support and ePTFE membrane to a temperature sufficient to fuse the membrane layers; and

cooling the resulting assembly.

22. The method of Claim 21, wherein an ePTFE membrane is contacted to each of the lumenal and exterior surfaces of the tubular wire support, such that the wire support is substantially embedded between the ePTFE membranes after the heating and cooling steps.

23. The method of Claim 21, wherein prior to the contacting step, the wire is coated a thermoplastic adhesive.

Fig. 1

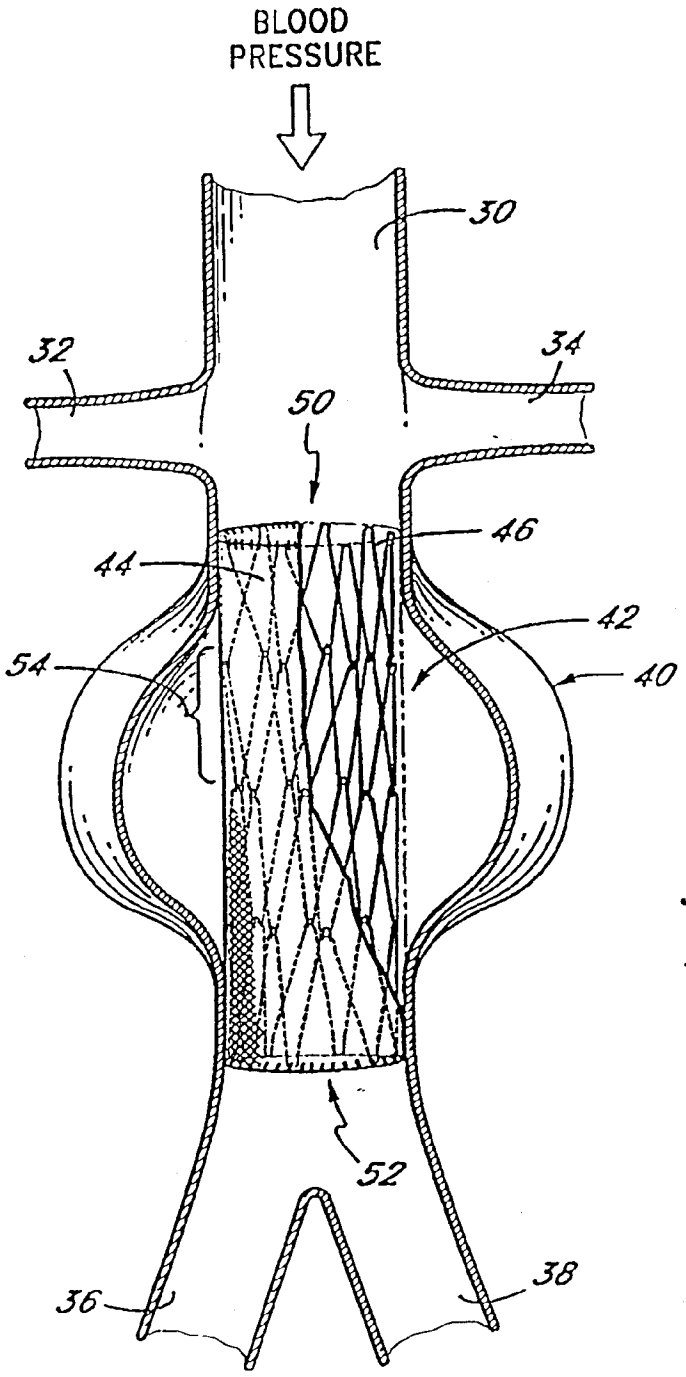
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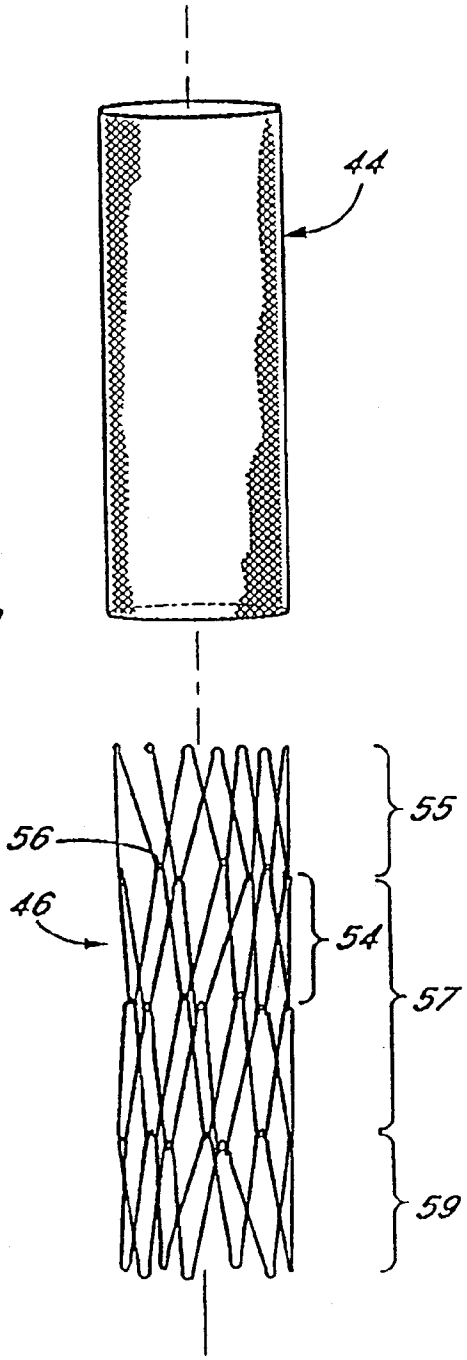
Fig. 2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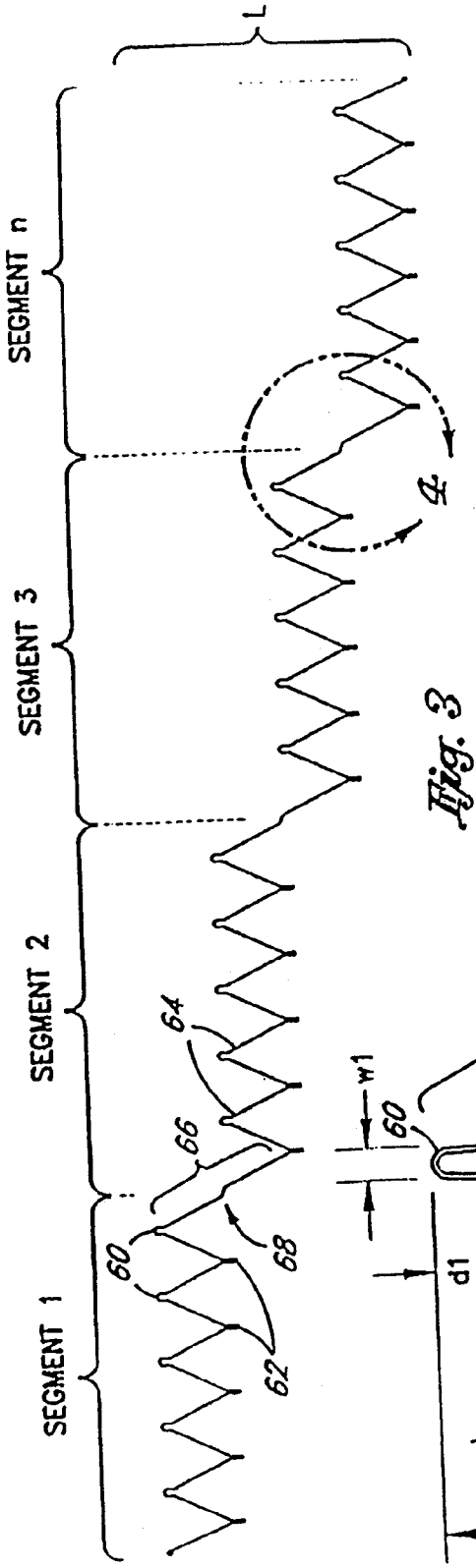
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SEGMENT 2
SEGMENT 1
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Fig. 3

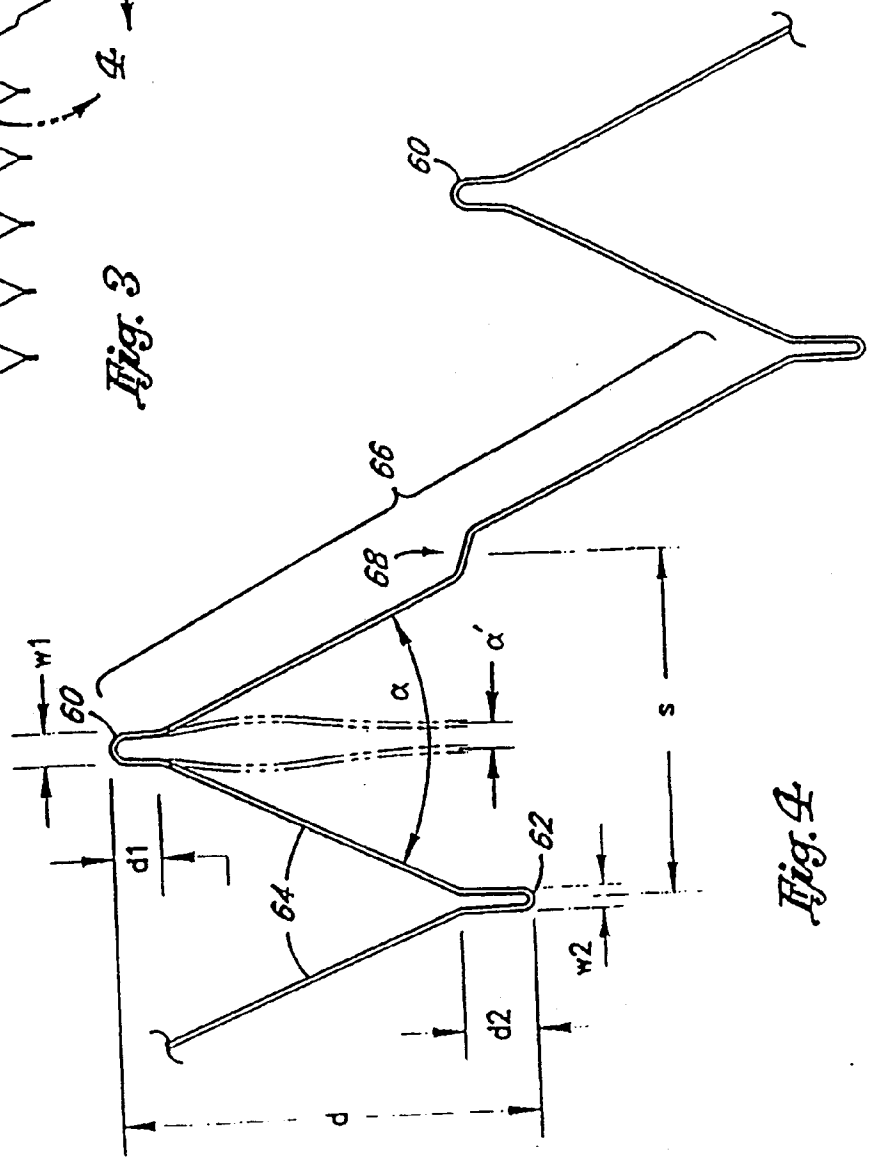
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Fig. 4

Fig. 5

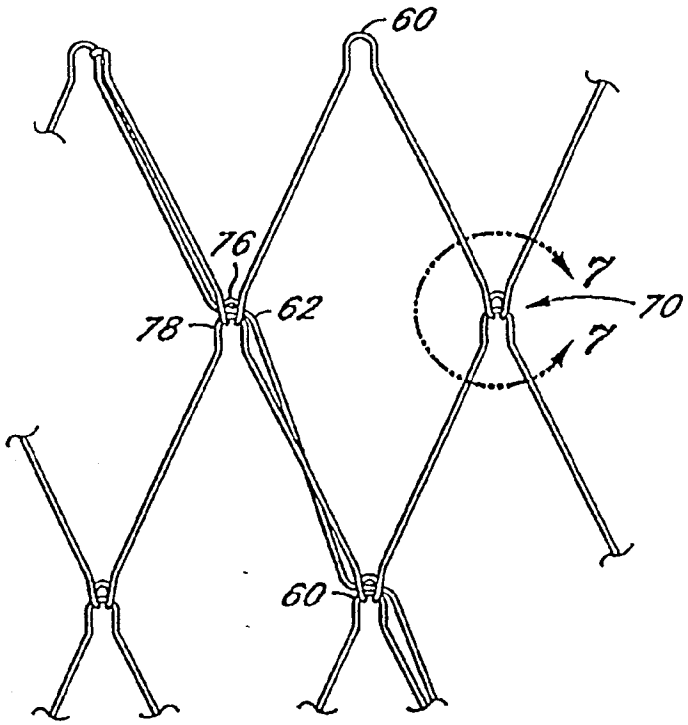


Fig. 6

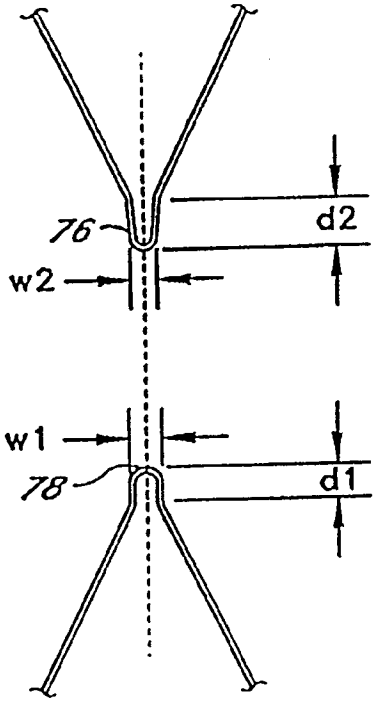


Fig. 7

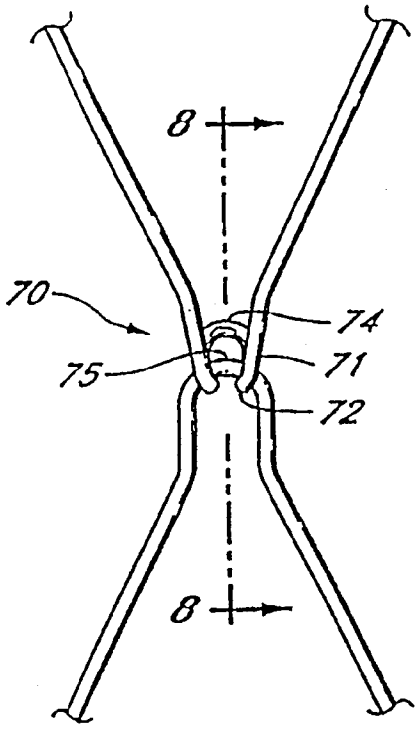


Fig. 8

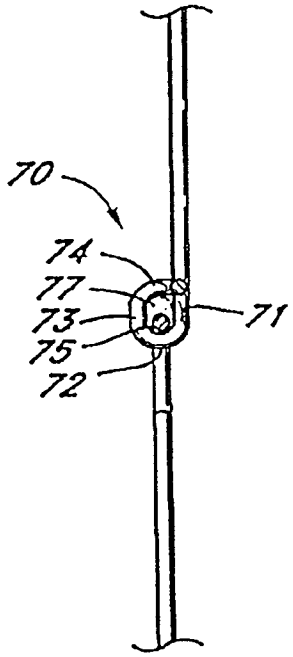


Fig. 6A

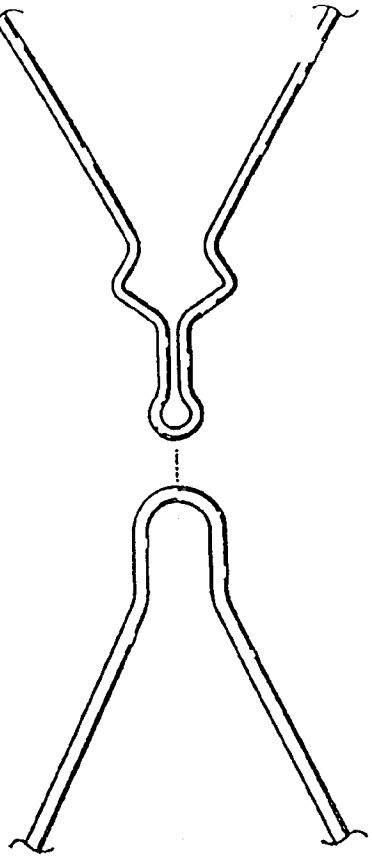


Fig. 7A

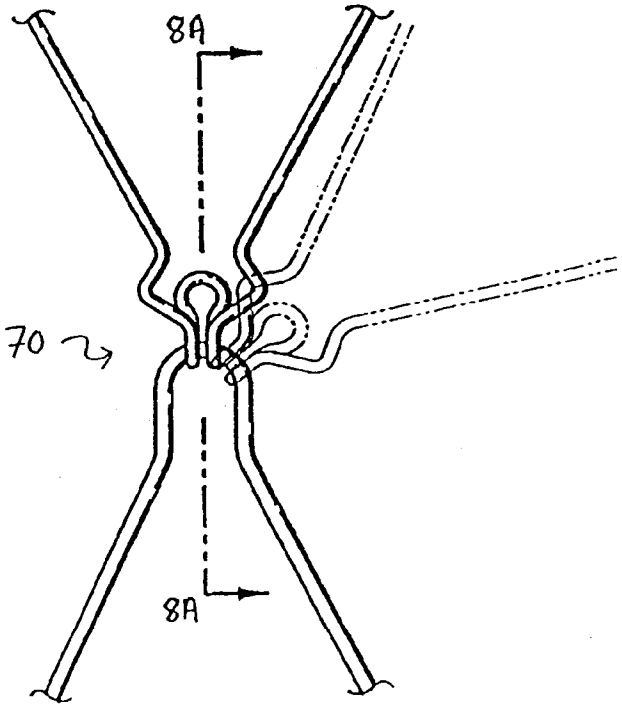
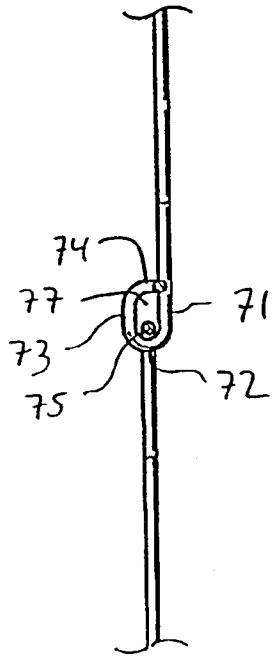


Fig. 8A



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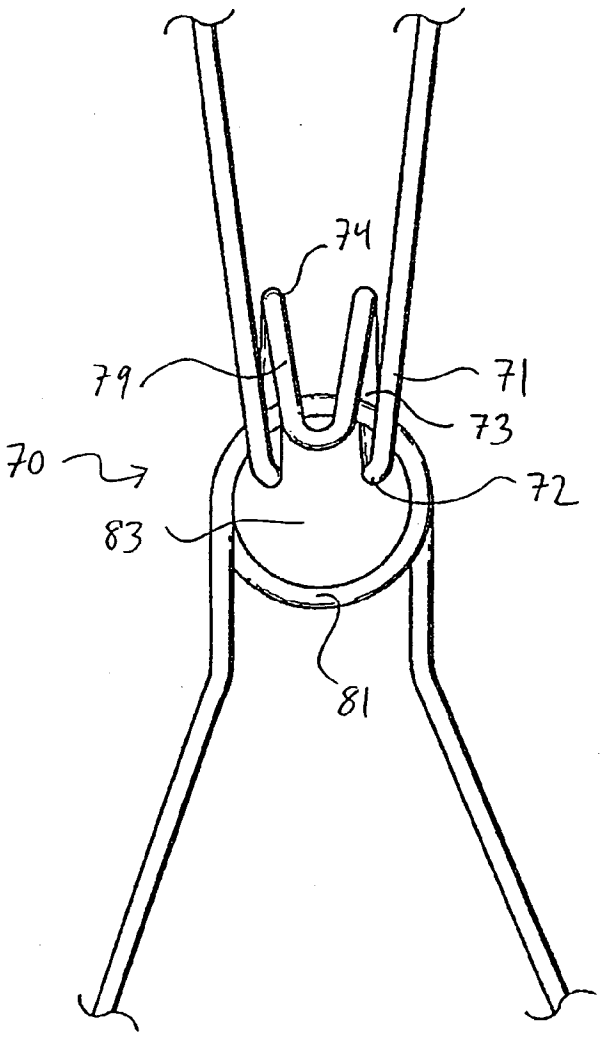

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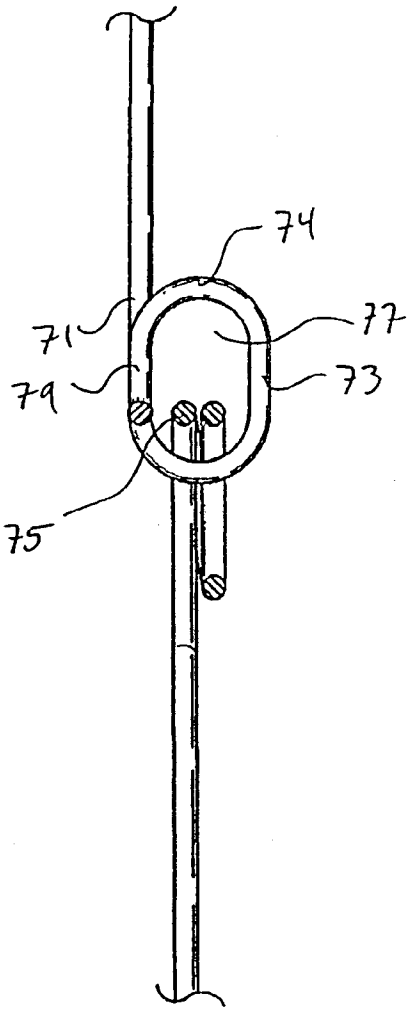
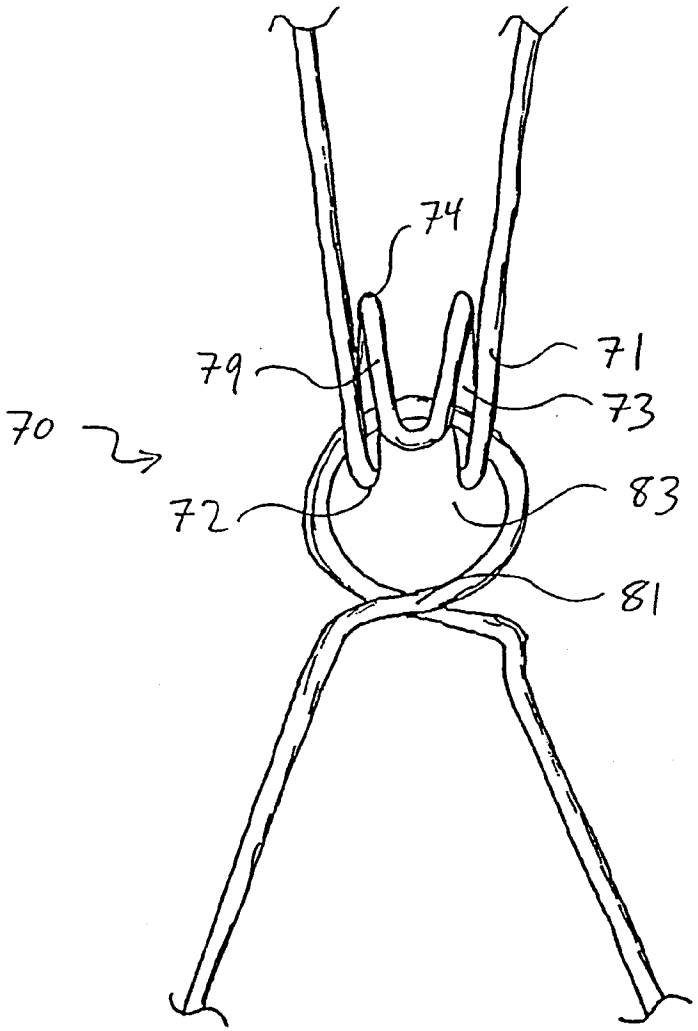


Fig. 7C



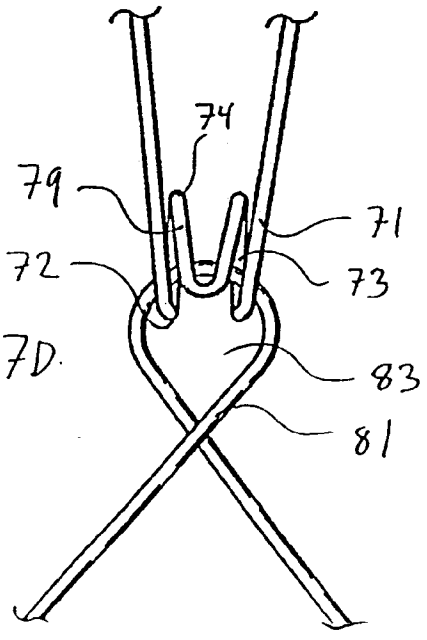
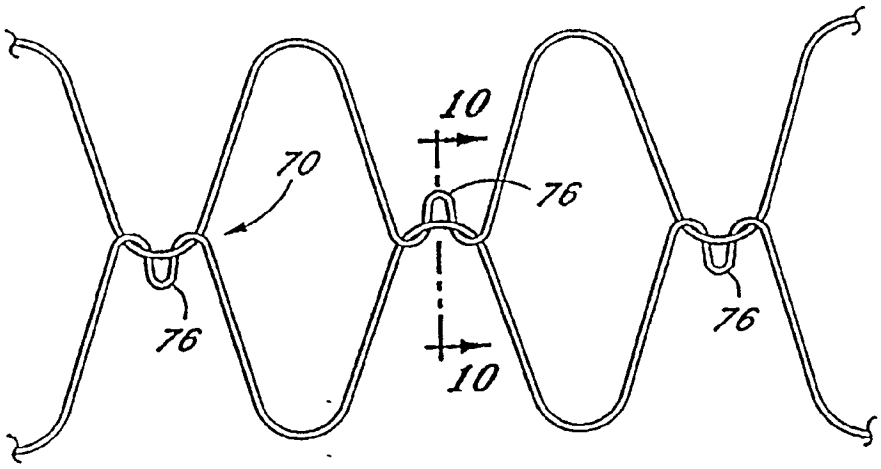


Fig. 7D

Fig. 9



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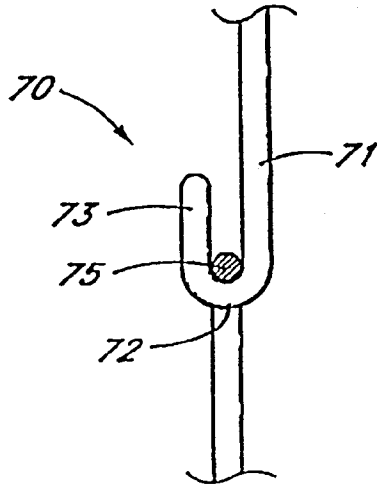

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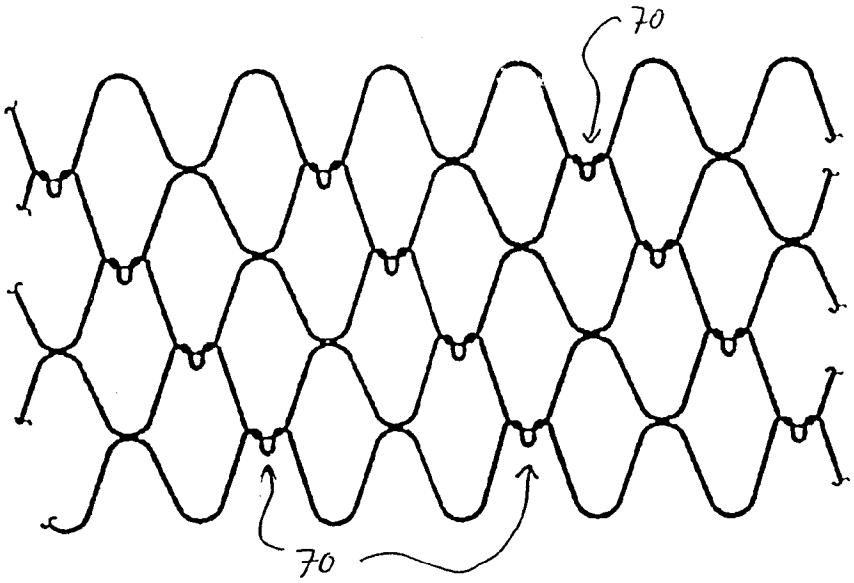

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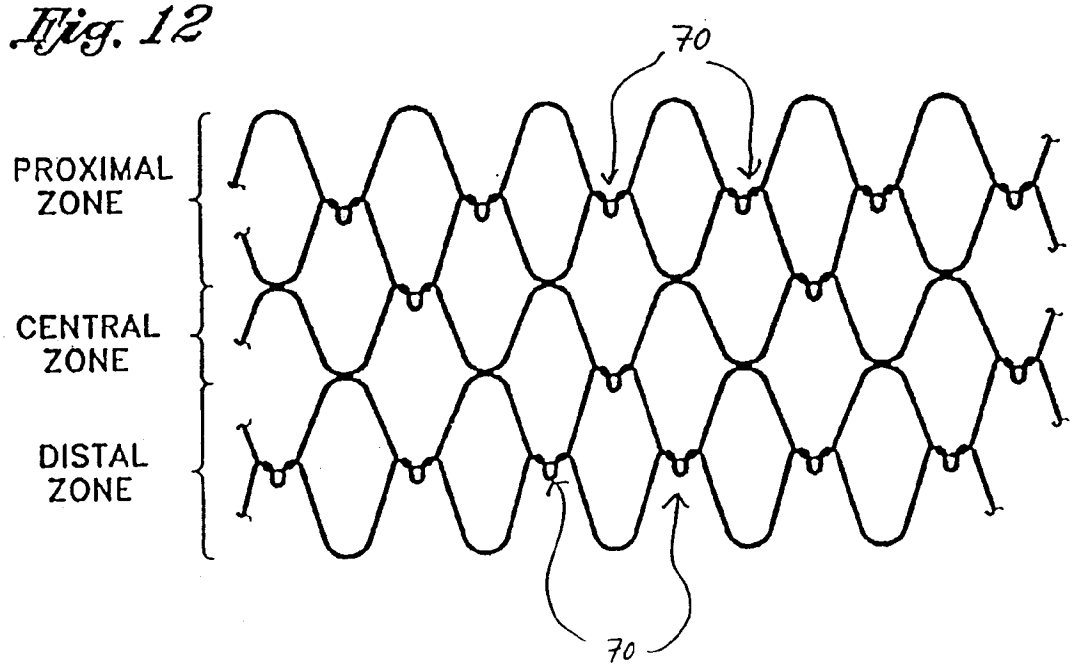
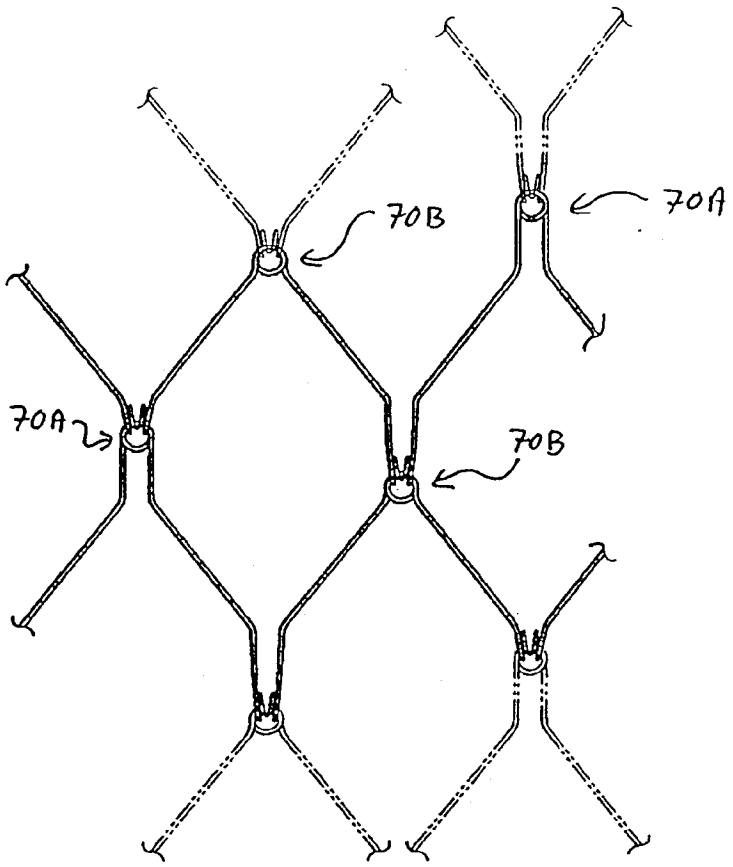


Fig. 12A



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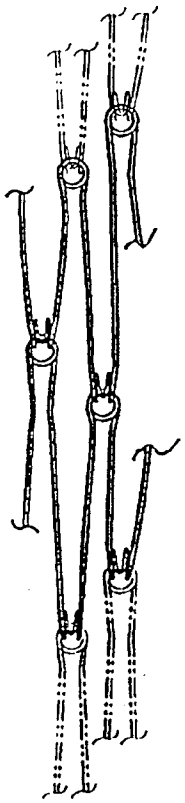
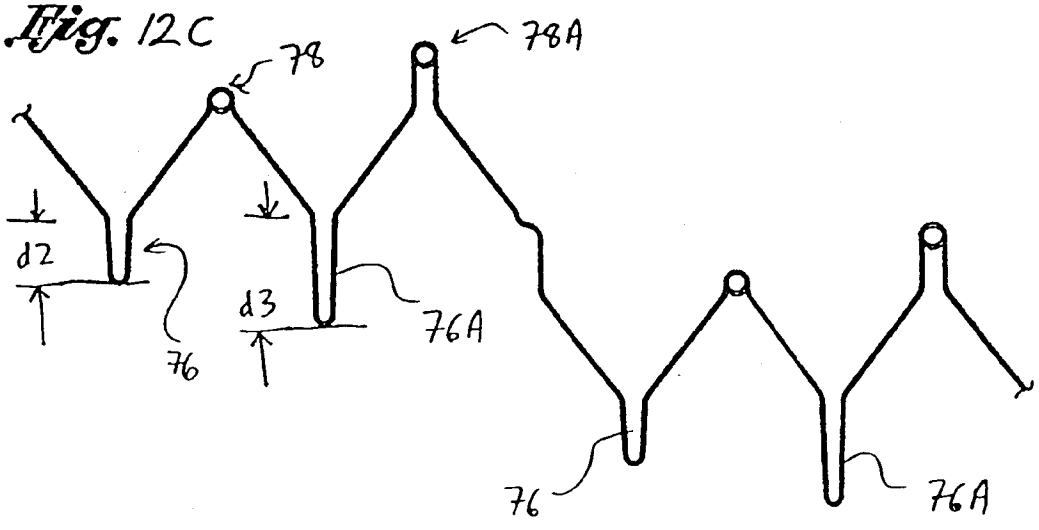


Fig. 12C



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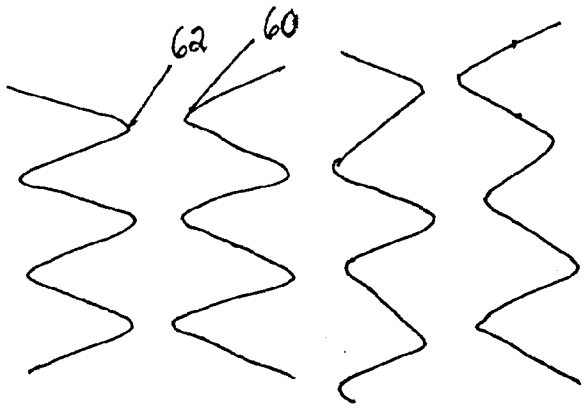

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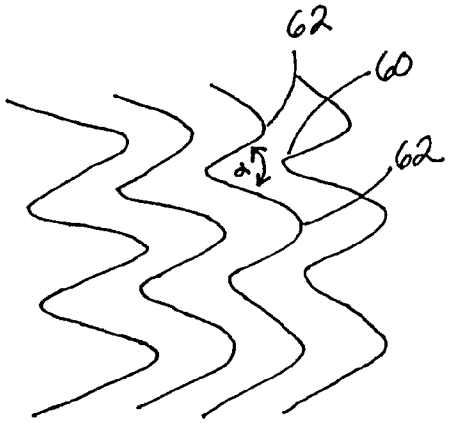

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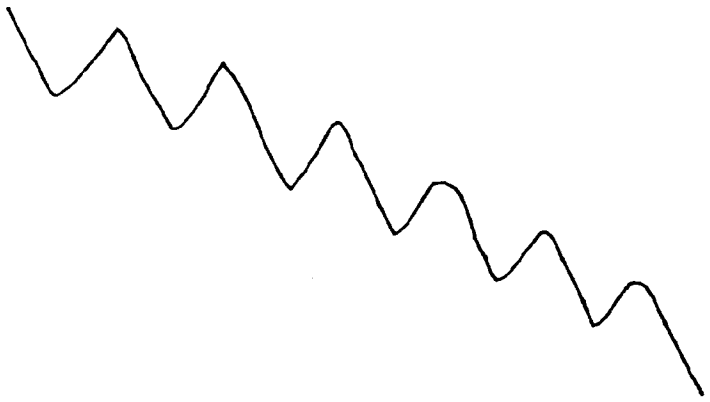

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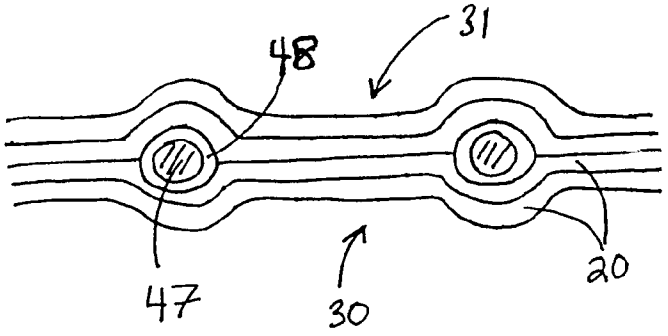

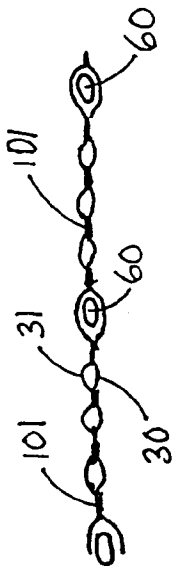

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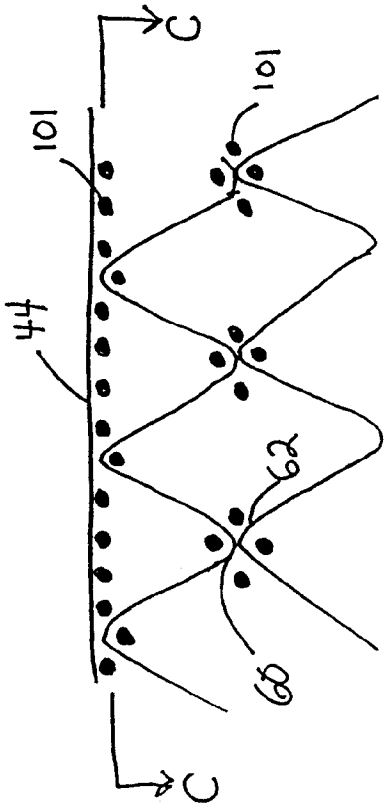

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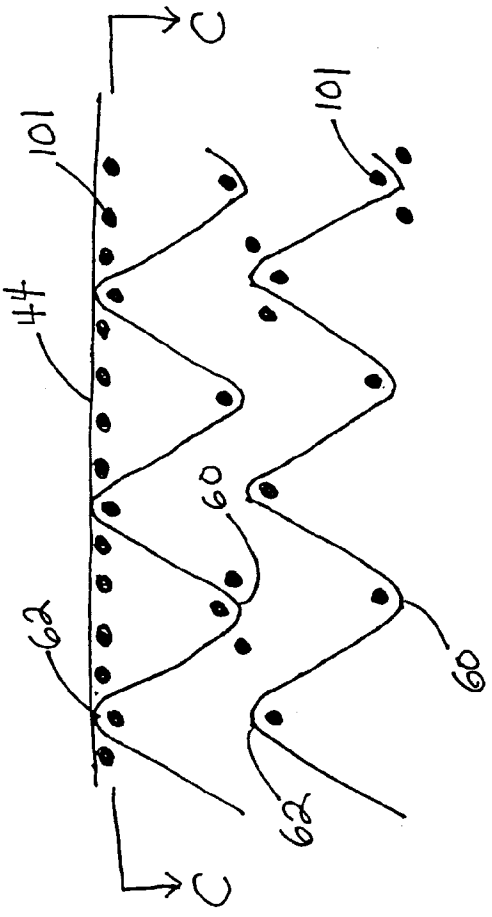
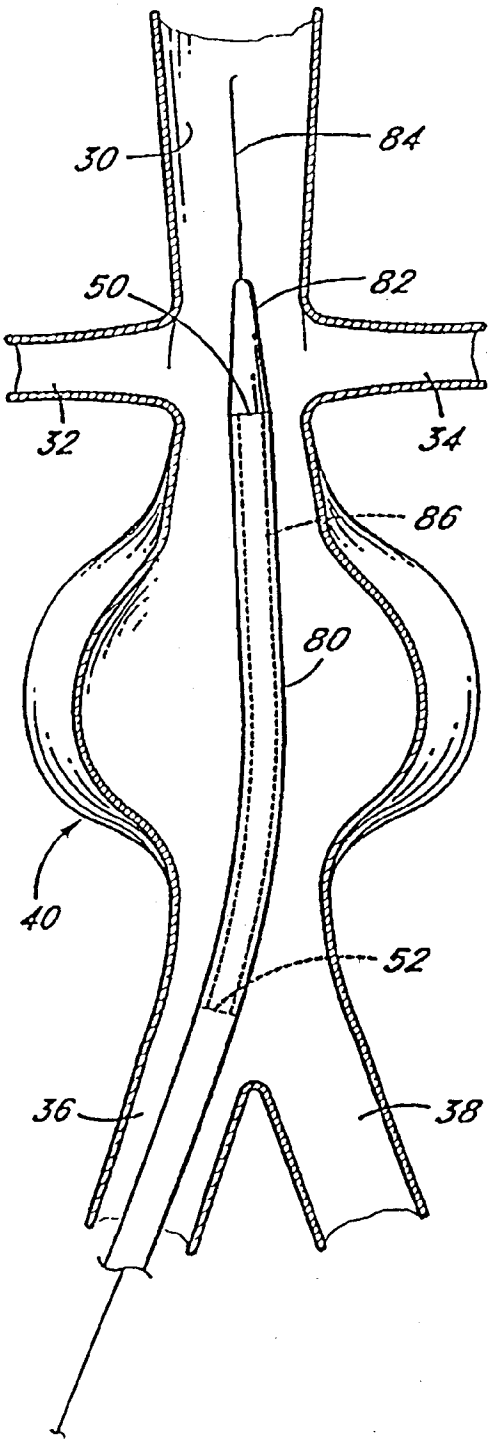


Fig. 15B

Fig. 16



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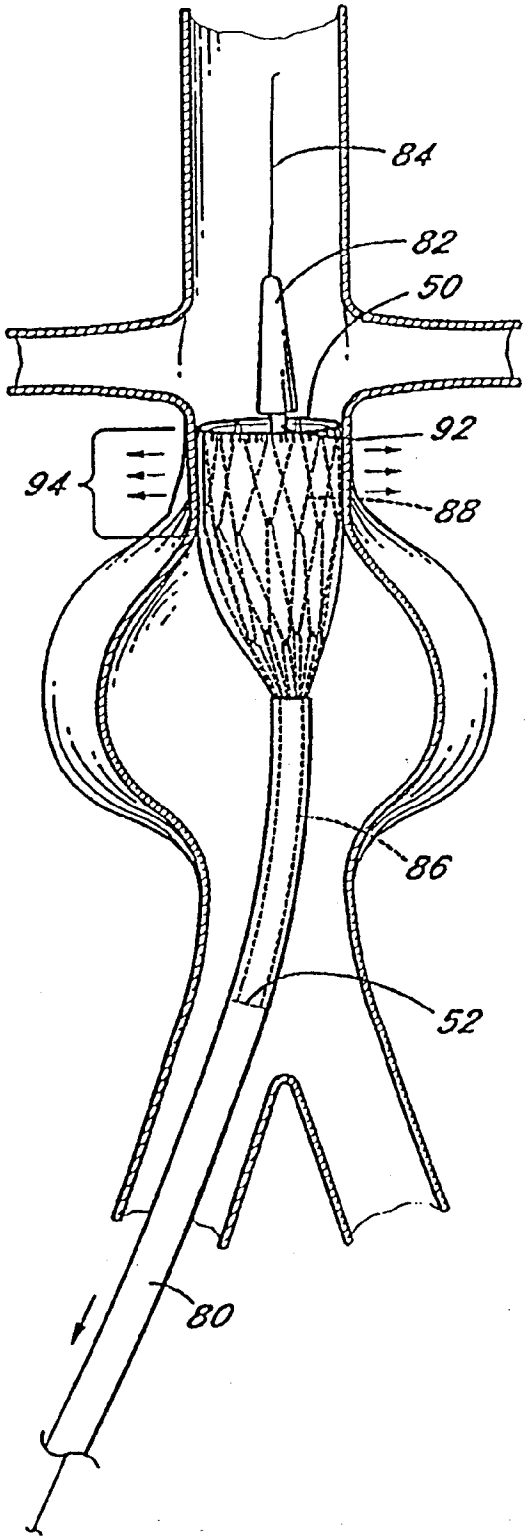

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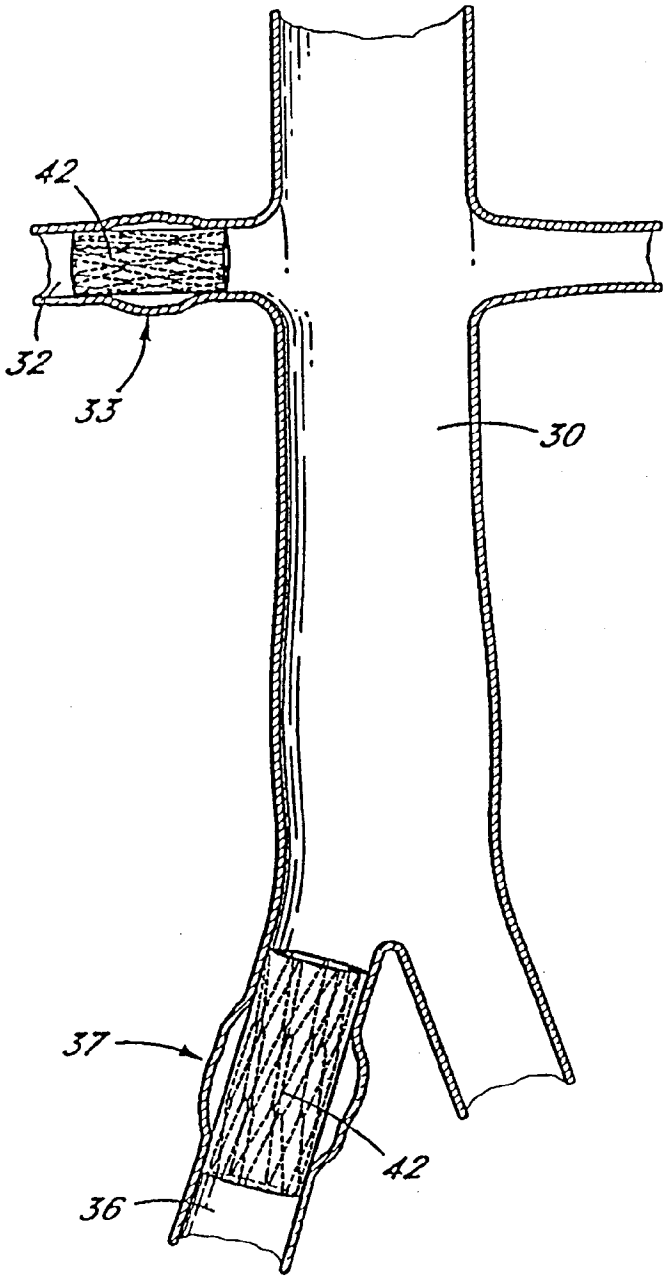

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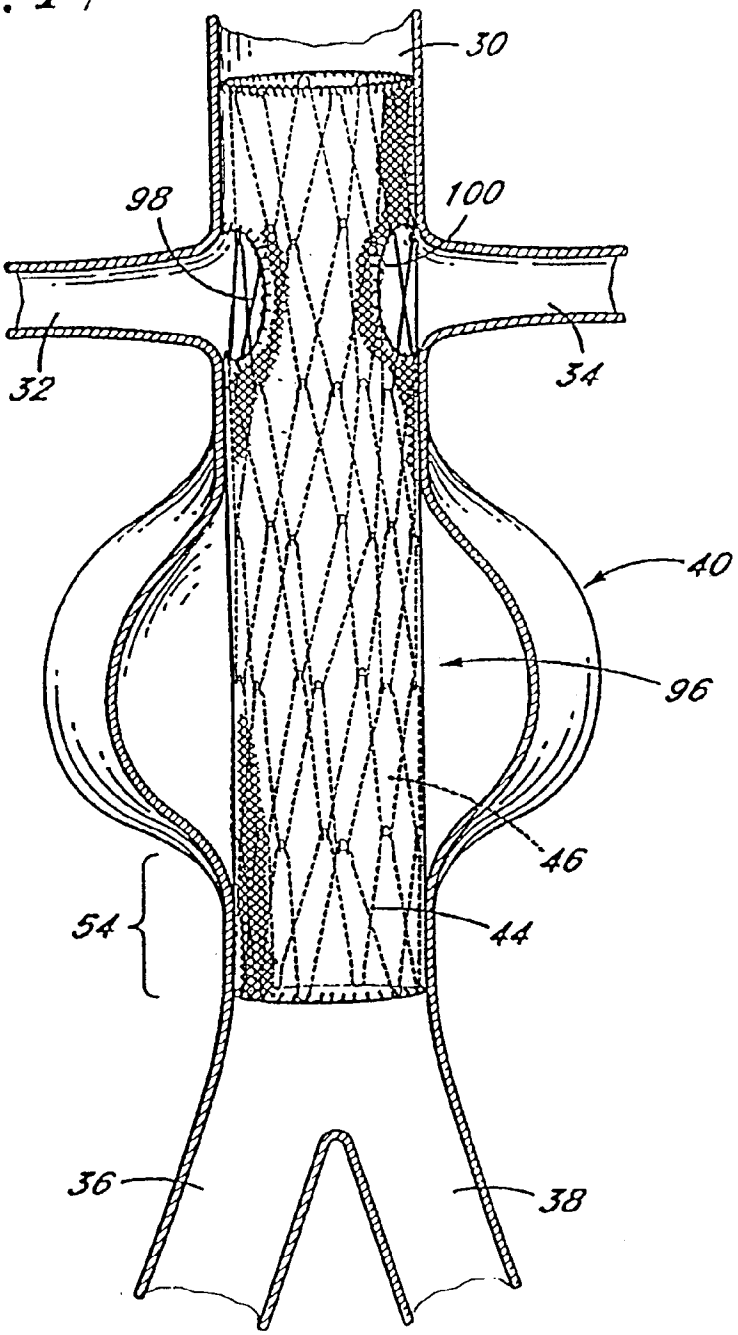

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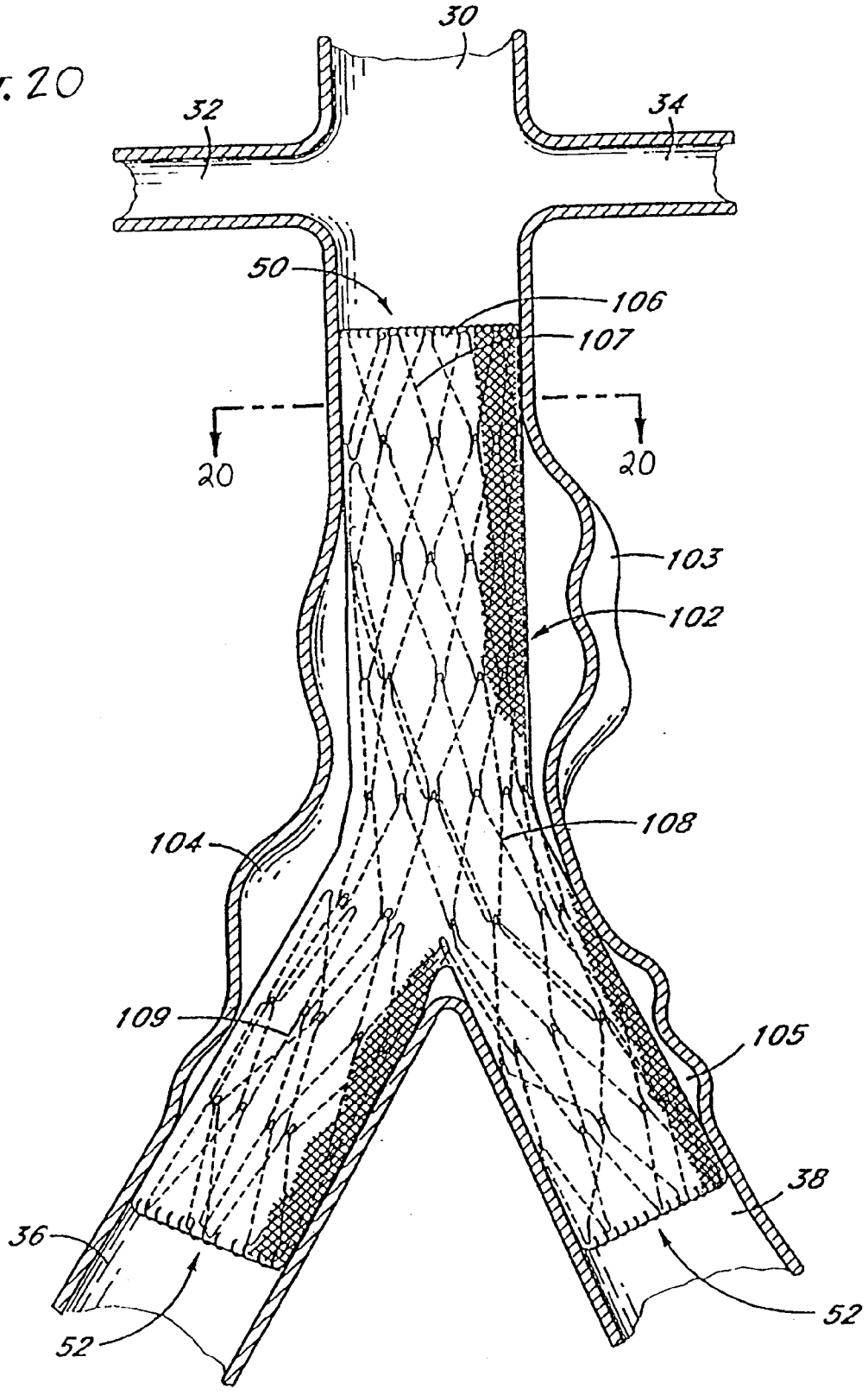

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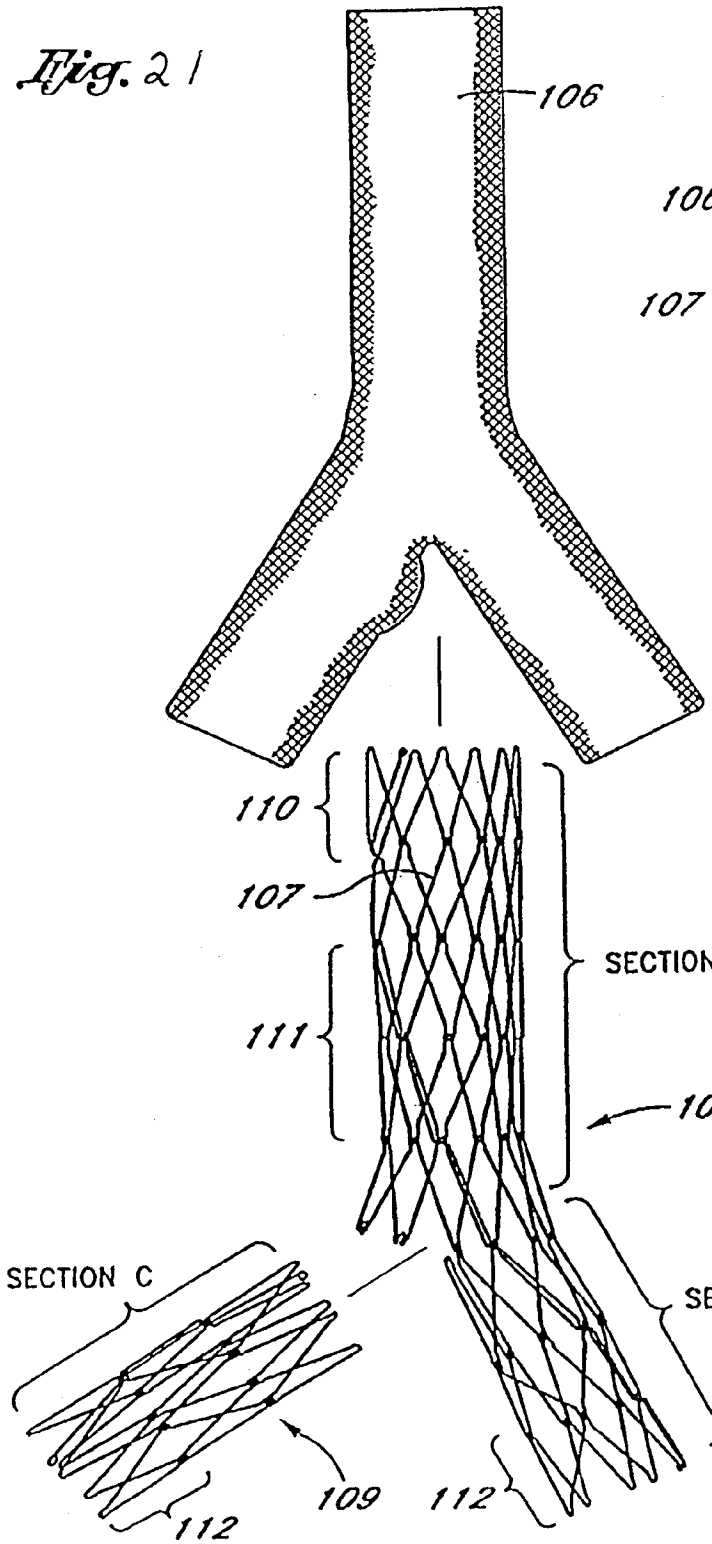
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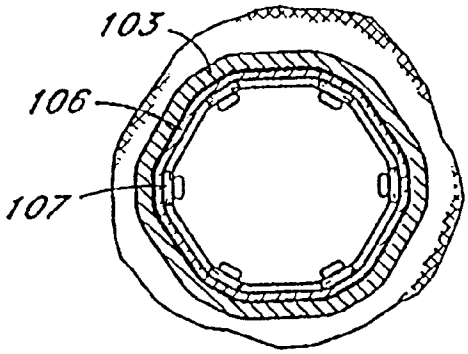
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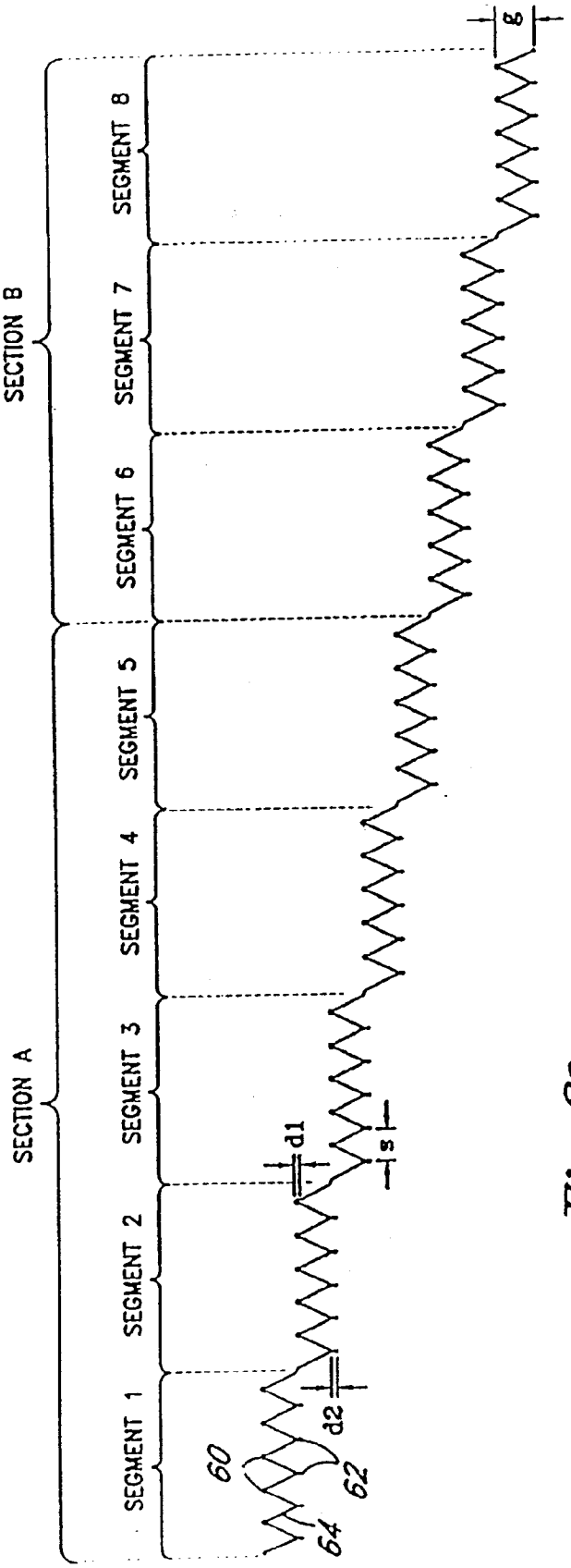
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Fig. 23

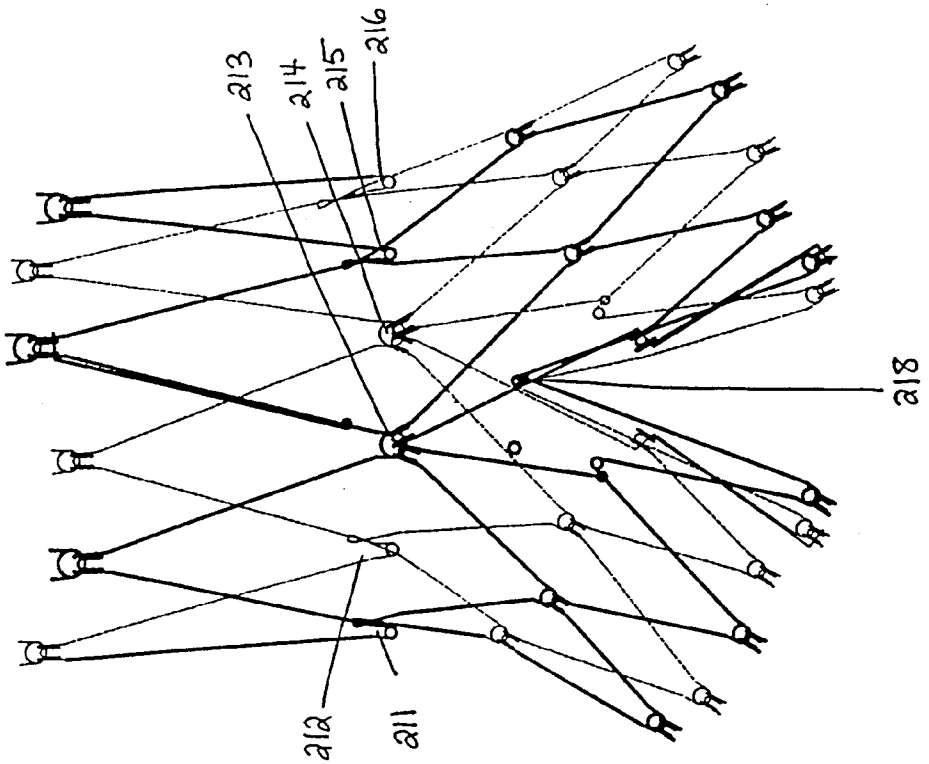
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Fig. 25

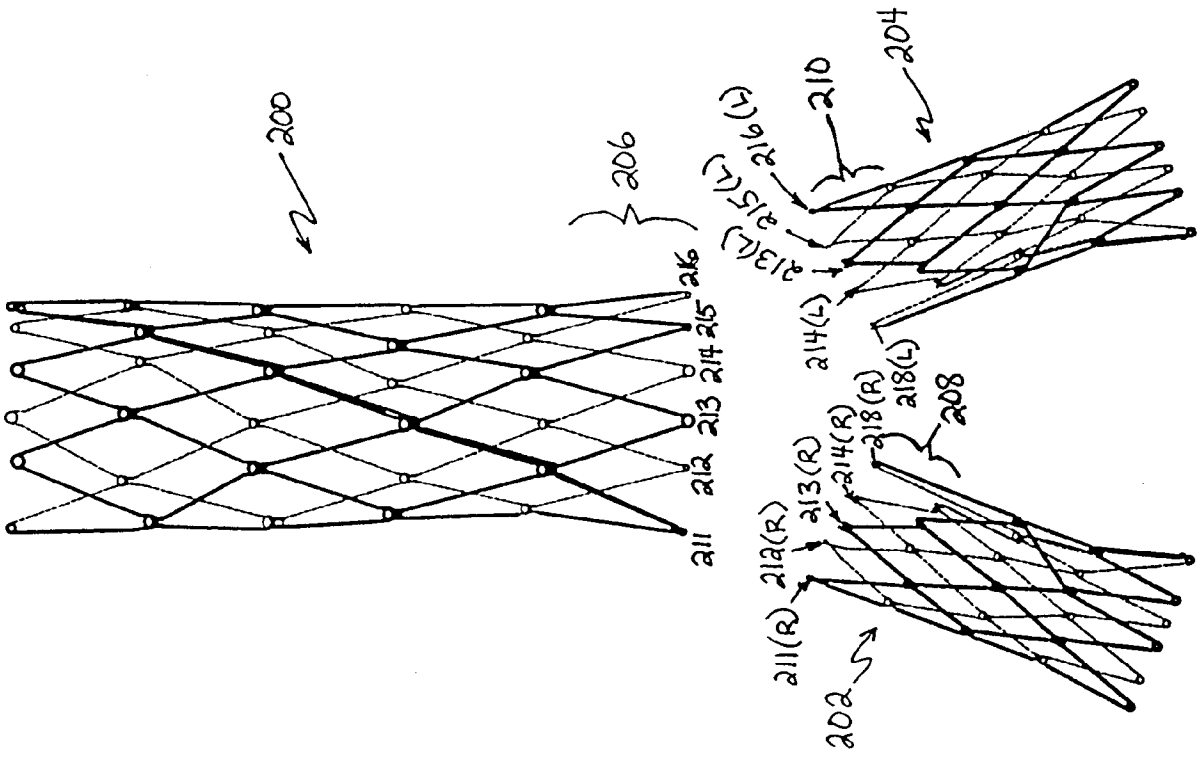
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Fig. 24

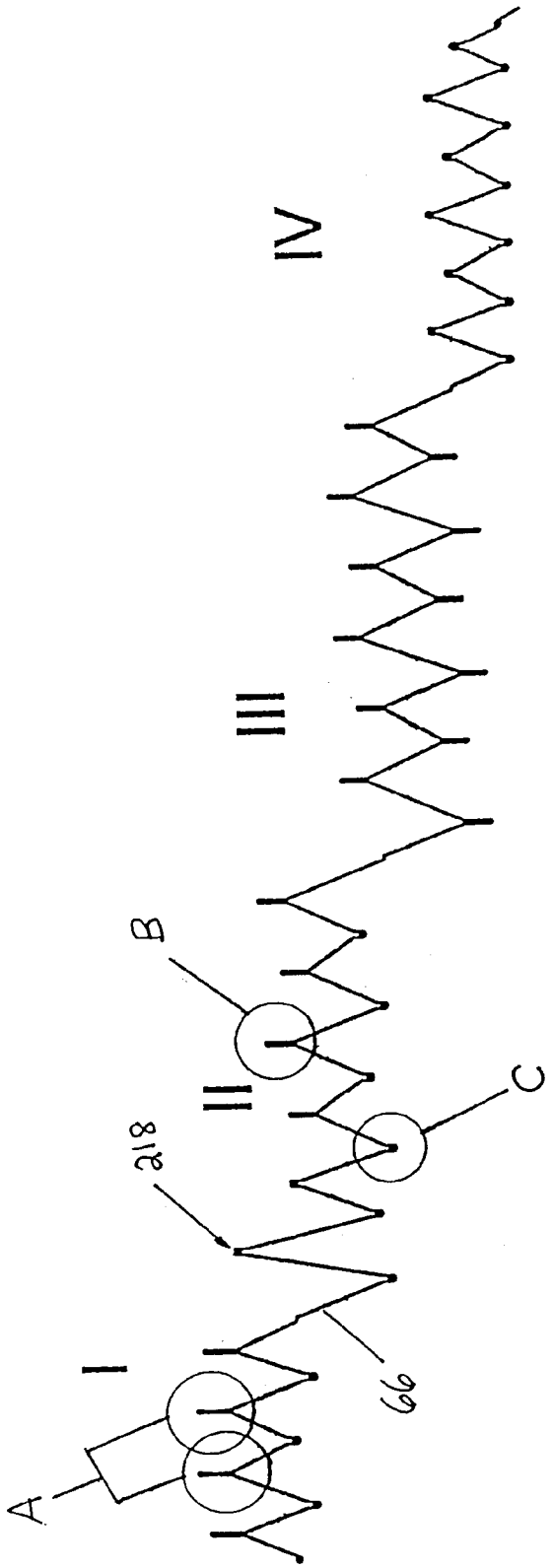

Fig. 26

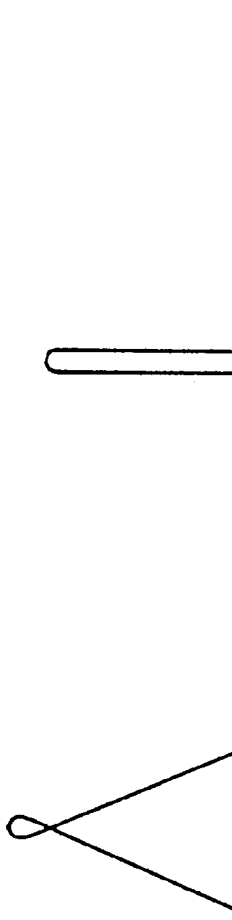

Fig. 27A

Fig. 27B

Fig. 27C

INTERNATIONAL SEARCH REPORT

Inte ional Application No
PCT/US 00/30881

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61F2/06

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
WPI Data, EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 99 47077 A (MEADOX MEDICALS, INC.) 23 September 1999 (1999-09-23)	1-5,10, 13-16, 19,21,22
Y	the whole document	6,7,11, 12,17,23
Y	US 5 749 880 A (BANAS ET AL) 12 May 1998 (1998-05-12) column 12, line 30 - line 43	6,7,17
Y	US 5 928 279 A (SHANNON ET AL) 27 July 1999 (1999-07-27) column 9, line 12 - line 20	11,12,23
X	WO 99 44536 A (ENDOLGIX, INC.) 10 September 1999 (1999-09-10) the whole document	1,2,4, 10,20

☐ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

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"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

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"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
23 February 2001	02/03/2001

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL – 2280 HV Rijswijk Tel. (+31–70) 340–2040, Tx. 31 651 epo nl, Fax: (+31–70) 340–3016	Smith, C

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Form PCT/ISA/210 (second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

Information on patent family members

Inte .ional Application No
PCT/US 00/30881

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 9947077 A	23-09-1999	US 6001125 A	14-12-1999
		AU 3008599 A	11-10-1999
		EP 1063943 A	03-01-2001
US 5749880 A	12-05-1998	US 6124523 A	26-09-2000
		CA 2215027 A	19-09-1996
		DE 69518337 D	14-09-2000
		DE 69518337 T	01-02-2001
		EP 0814729 A	07-01-1998
		ES 2151082 T	16-12-2000
		JP 10510196 T	06-10-1998
		US 6004348 A	21-12-1999
		WO 9628115 A	19-09-1996
		ZA 9510700 A	25-11-1996
US 5928279 A	27-07-1999	AU 712190 B	28-10-1999
		AU 3505697 A	21-01-1998
		BR 9710100 A	07-12-1999
		CA 2259543 A	08-01-1998
		CN 1228690 A	15-09-1999
		EP 0959813 A	01-12-1999
		JP 2000508216 T	04-07-2000
		WO 9800090 A	08-01-1998
WO 9944536 A	10-09-1999	US 6077296 A	20-06-2000
		AU 7960098 A	20-09-1999
		EP 1059893 A	20-12-2000